

EXHIBIT 1

<p style="text-align: right;">Page 1</p> <p>1 UNITED STATES DISTRICT COURT 2 FOR THE DISTRICT OF NEW JERSEY 3 MDL No. 2875 4 5 IN RE: VALSARTAN, PRODUCTS) 6 LIABILITY LITIGATION) 7) 8) 9 TESTIMONY OF:) 10 Stephen Hecht, Ph.D.) 11) 12 ----- 13 August 17, 2021 14 9:00 a.m. 15 16 TRANSCRIPT of the stenographic notes of the video 17 recorded proceedings in the above-entitled matter, as 18 taken by and before Sara K. Killian, a Registered 19 Professional Reporter, Certified Court Reporter and Notary 20 Public, remotely via Zoom videoconferencing. 21 22 23 24 25</p>	<p style="text-align: right;">Page 3</p> <p>1 A P P E A R A N C E S: (cont'd) 2 3 PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP 4 Attorneys for Mylan Pharmaceuticals Inc., Mylan 5 Laboratories Ltd., Mylan Inc., and Mylan N.V. 6 One Oxford Centre 7 301 Grant Street 8 Pittsburgh, Pennsylvania 15219 9 BY: CLEM TRISCHLER, ESQ. 10 FRANK STOY, ESQ. 11 TIFFANY GRIMES, Paralegal 12 13 14 15 BARNES & THORNBURG, LLP 16 Attorneys for CVS and Rite Aid 17 11 South Meridian Street 18 Indianapolis, Indiana 46204 19 BY: KARA KAPKE, ESQ. 20 21 22 23 24 25</p>
<p style="text-align: right;">Page 2</p> <p>1 A P P E A R A N C E S : 2 3 MAZIE SLATER KATZ & FREEMAN, LLC 4 Attorneys for Plaintiffs 5 103 Eisenhower Parkway, Second Floor 6 Roseland, New Jersey 07068 7 BY: ADAM SLATER, ESQ. 8 CHRISTOPHER GEDDIS, ESQ. 9 JULIA SLATER, ESQ. 10 11 12 13 MARTIN HARDING & MAZZOTTI, LLP 14 Attorneys for Plaintiffs 15 100 Park Avenue Center, 16th Floor 16 New York, New York 10017 17 BY: ROSEMARIE RIDDELL BOGDAN, ESQ. 18 19 20 GOLOMB & HONIK, PC 21 Attorneys for Plaintiffs 22 1835 Market Street, #2900 23 Philadelphia, Pennsylvania 19103 24 BY: RUBEN HONIK, ESQ. 25</p>	<p style="text-align: right;">Page 4</p> <p>1 A P P E A R A N C E S: (cont'd) 2 3 GREENBERG TRAURIG, LLP 4 Attorneys for Teva Pharmaceuticals USA 5 333 SE 2nd Avenue, Suite 4400 6 Miami, Florida 33131 7 BY: STEPHEN FOWLER, ESQ. 8 VICTORIA LOCKARD, ESQ. 9 10 11 12 WALSH PIZZI O'REILLY FALANGA 13 Attorneys for Teva Pharmaceuticals USA 14 One Riverfront Plaza 15 1037 Raymond Boulevard, Suite 600 16 Newark, New Jersey 07102 17 BY: CHRISTINE GANNON, ESQ. 18 19 20 CIPRIANI & WERNER, PC 21 Attorneys for Aurobindo Pharma USA, Inc. 22 450 Sentry Parkway, Suite 200 23 Blue Bell, Pennsylvania 19422 24 BY: JILL FERTEL, ESQ. 25</p>

<div>Page 5</div> <div>1 A P P E A R A N C E S: (cont'd)</div> <div>2</div> <div>3 DUANE MORRIS, LLP</div> <div>4 Attorneys for Prinston Pharmaceutical Inc., Zhejiang</div> <div>5 Huahai Pharmaceutical Co., Ltd., Solco Healthcare</div> <div>6 US, LLC, Huahai US, Inc., Walmart Stores, Inc.,</div> <div>7 and Walgreen Co.</div> <div>8 1875 NW Corporate Boulevard, Suite 300</div> <div>9 Boca Raton, Florida 33431</div> <div>10 BY: PATRICK C. GALLAGHER, ESQ.</div> <div>11</div> <div>12</div> <div>13</div> <div>14</div> <div>15 HINSHAW & CULBERTSON, LLP</div> <div>16 Attorneys for HJ Harkins and Scigen</div> <div>17 53 State Street, 27th Floor</div> <div>18 Boston, Massachusetts 02109</div> <div>19 BY: KATHLEEN E. KELLY, ESQ.</div> <div>20</div> <div>21</div> <div>22</div> <div>23</div> <div>24</div> <div>25</div>	<div>Page 7</div> <div>1 A P P E A R A N C E S: (cont'd)</div> <div>2</div> <div>3 HUSCH BLACKWELL, LLP</div> <div>4 Attorneys for Express Script, Inc.</div> <div>5 190 Carondelet Plaza, Suite 600</div> <div>6 St. Louis, Missouri 63105</div> <div>7 BY: JAMES SPRUNG, ESQ.</div> <div>8</div> <div>9</div> <div>10</div> <div>11</div> <div>12</div> <div>13</div> <div>14 ALSO PRESENT:</div> <div>15 WILLIAM MILLER, Veritext Videographer</div> <div>16</div> <div>17</div> <div>18</div> <div>19</div> <div>20</div> <div>21</div> <div>22</div> <div>23</div> <div>24</div> <div>25</div>
<div>Page 6</div> <div>1 A P P E A R A N C E S: (cont'd)</div> <div>2</div> <div>3 FALKENBERG IVES, LLP</div> <div>4 Attorneys for Humana Pharmacy</div> <div>5 230 W. Monroe, Suite 2220</div> <div>6 Chicago, Illinois 60606</div> <div>7 BY: KIRSTEN IVES, ESQ.</div> <div>8</div> <div>9</div> <div>10</div> <div>11 HILL WALLACK, LLP</div> <div>12 Attorneys for Hetero Drugs Ltd. and Hetero Labs Ltd.</div> <div>13 21 Roszel Road</div> <div>14 Princeton, New Jersey 08543</div> <div>15 BY: NAKUL Y. SHAH, ESQ.</div> <div>16 CARLOS S. DeHART, ESQ.</div> <div>17</div> <div>18</div> <div>19</div> <div>20 BUCHANAN INGERSOLL & ROONEY, PC</div> <div>21 Attorneys for Albertson's LLC</div> <div>22 227 West Trade Street, Suite 600</div> <div>23 Charlotte, North Carolina 28202</div> <div>24 BY: CHRISTOPHER B. HENRY, ESQ.</div> <div>25</div>	<div>Page 8</div> <div>1 I N D E X</div> <div>2</div> <div>3 WITNESS EXAMINATION BY PAGE</div> <div>4 Dr. Hecht Mr. Trischler 12</div> <div>5 Mr. Fowler 309</div> <div>6 Ms. Kapke 390</div> <div>7</div> <div>8 E X H I B I T S</div> <div>9 EXHIBITS DESCRIPTION PAGE</div> <div>10 Exhibit 1 Expert Report of Stephen Hecht, Ph.D., 7/6/21 18</div> <div>11</div> <div>12 Exhibit 2 Curriculum vitae of Stephen Hecht, Ph.D. 33</div> <div>13 Exhibit 3 "Plaintiffs' Disclosure of Cancer Types" 36</div> <div>14</div> <div>15 Exhibit 4 "Comparative Tumorigenicity and DNA Methylation in F344 Rats by 4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanone and N-nitrosodimethylamine" by Stephen Hecht, et al 67</div> <div>16</div> <div>17</div> <div>18</div> <div>19 Exhibit 5 Invoices 102</div> <div>20 Exhibit 6 "Pharmacokinetics of N-nitrosodimethylamine in beagles" by C.T. Gombard, et al 113</div> <div>21</div> <div>22</div> <div>23</div> <div>24</div> <div>25</div>

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1	E X H I B I T S		1	THE VIDEOGRAPHER: Good morning. We	
2	EXHIBITS DESCRIPTION PAGE		2	are going on the record at 9:13 a.m. on	
3	Exhibit 15 "High-Fat Foods and the 219		3	August 17, 2021. This is media unit one of	
4	Risk of Lung Cancer" by		4	the video recorded deposition of Steven	
5	Marc T. Goodman, et al		5	Hecht, PhD in the matter of the valsartan,	
6	Exhibit 16 "Risk of Colorectal and 224		6	losartan case.	
7	Other Gastro-Intestinal		7	My name is William Miller from the	
8	Cancers After Exposure to		8	firm Veritext Legal Solutions. I'm the	
9	Nitrate, Nitrite and		9	videographer. The court reporter is Sara	
10	N-Nitroso Compounds: A		10	Killian from the firm Veritext Legal	
11	Follow-Up Study" by Paul		11	Solutions.	
12	Knekt, et al		12	All counsel is noted on the	
13	Exhibit 17 "N-nitroso Compounds and 234		13	stenographic record.	
14	Cancer Incidence: The		14	Will the court reporter please swear	
15	European Prospective		15	in the witness and we can begin?	
16	Investigation into Cancer		16	STEPHEN HECHT, P h D, after having	
17	and Nutrition" by Yet Hua		17	first been duly sworn, was examined and testified	
18	Loh, et al		18	as follows:	
19	Exhibit 18 "Dietary Nitrates, 243		19	MR. TRISCHLER: Dr. Hecht, good	
20	Nitrites, and		20	morning.	
21	Nitrosamines Intake and		21	THE WITNESS: Good morning.	
22	the Risk of Gastric		22	MR. TRISCHLER: Before we begin, I	
23	Cancer: A Meta-Analysis"		23	just want to confirm on the record an	
24	by Peng Song, et al		24	agreement that Mr. Slater and I reached	
25	Exhibit 19 Exhibit 2: Documents 261		25	before the beginning of this deposition.	
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	the Risk of Cancer" by				
	Willy Gomm, et al				

<p style="text-align: right;">Page 13</p> <p>1 This is the time and place set for 2 the deposition of Dr. Steven Hecht. Dr. 3 Hecht issued a report dated July 6th, 2021 4 and we're here today to take his deposition 5 on issues relating to causation opinions that 6 Dr. Hecht has or may have or wishes to 7 testify about in connection with the 8 valsartan multi-district litigation. 9 The report of July 6, 2021 includes 10 opinions and potential areas of testimony 11 that go beyond the issue of causation and get 12 into what I would consider to be other 13 liability issues. 14 I believe the agreement of the 15 parties is that any inquiry of Dr. Hecht on 16 those issues unrelated to causation will be 17 deferred until a later period of time in 18 connection with this multi-district 19 litigation. My deposition of Dr. Hecht and 20 the defendant's deposition of Dr. Hecht today 21 will be limited to causation opinions. 22 Is that fair, Mr. Slater? 23 MR. SLATER: Yes. This deposition 24 will not address liability, but will address 25 general causation.</p>	<p style="text-align: right;">Page 15</p> <p>1 myself and perhaps some other lawyers are going to 2 be asking you questions today and the answers that 3 you are providing are answers under oath and under 4 penalty of perjury. 5 Do you understand that? 6 A. Yes. 7 Q. I presume then that the answers that 8 you provide to my questions today will be honest 9 and truthful and to the best of your ability? 10 A. Yes. 11 Q. Tell us your full name, sir. 12 A. Stephen Samuel Hecht. 13 Q. What's your professional address, 14 Dr. Hecht? 15 A. Masonic Cancer Center, University of 16 Minnesota, Minneapolis, 55455. 17 Q. Where are you physically located 18 today as you give your deposition? 19 A. I'm in the Cancer and Cardiovascular 20 Research Building on the university campus. 21 Q. And the university campus being the 22 campus of the University of Minnesota? 23 A. Yes. 24 Q. Is anyone in the room with you as you 25 give your deposition testimony today?</p>
<p style="text-align: right;">Page 14</p> <p>1 MR. TRISCHLER: Understood and 2 agreed. 3 Thank you. 4 EXAMINATION BY 5 MR. TRISCHLER: 6 Q. Dr. Hecht, as I mentioned just a 7 moment ago, my name is Clem Trischler. I'm an 8 attorney. I represent the Mylan defendants and 9 the Defendants' Executive Committee in the 10 valsartan multi-district litigation that's pending 11 in the United States District Court for the 12 District of New Jersey. 13 You have been identified and 14 disclosed as an expert witness on behalf of the 15 plaintiffs in this litigation. 16 Are you aware of that? 17 A. Yes. 18 Q. Obviously, we're gathered to take 19 your deposition on causation issues relevant to 20 this litigation. I take it that you've given 21 deposition testimony before? 22 A. Yes. 23 Q. Given that fact, I'll refrain from 24 going into a detailed discussion of what the 25 deposition process is, but suffice it to say</p>	<p style="text-align: right;">Page 16</p> <p>1 A. No. 2 Q. Are you using a laptop or a desktop 3 computer to participate in this deposition? 4 A. It's a laptop. 5 Q. Do you have any other electronic 6 devices with you in the room as you give this 7 deposition other than the laptop on which you're 8 using to communicate with me? 9 A. Yes. I have my desktop and my phone. 10 Q. Would it be possible for you to turn 11 your desktop and phone off during the deposition? 12 A. I can. I was going to use the 13 desktop to view any of the papers that we're going 14 to discuss under sender say. I was given a link 15 to Novac Trial Services that would have the -- a 16 lot of the documents, so I thought that would be 17 convenient to look at, but I can turn it off. 18 Q. Well, that's -- that's all right. 19 What I want to make sure is that 20 you're not receiving communications from any 21 source on other electronic devices during the time 22 of the deposition. 23 A. No. 24 Q. All right. 25 What's your occupation?</p>

<p style="text-align: right;">Page 17</p> <p>1 A. I'm a professor. Walin Professor of 2 Cancer Prevention, University of Minnesota. 3 Q. You indicated in response to one of 4 my earlier questions that you were, in fact, 5 retained by the plaintiffs in the valsartan 6 litigation. 7 True? 8 A. Yes. 9 Q. When were you initially retained to 10 work for the plaintiffs in this litigation? 11 A. I don't have the exact date. It's 12 about two years ago. 13 Q. I was provided with some of your 14 invoices within the last couple of days and I'll 15 represent to you that the earliest entry that I 16 saw on your invoices was September 4, 2019. 17 A. Yes, that sounds about right. 18 Q. So would that entry refresh your 19 recollection as to the approximate period of time 20 when you were initially retained in this 21 litigation? 22 A. About two years. 23 Q. So about two years ago would be 24 September 2019; true? 25 A. Yes.</p>	<p style="text-align: right;">Page 19</p> <p>1 MR. TRISCHLER: That's why I'm asking 2 if he has it. I'd rather just work with the 3 doctor if he has it. 4 Q. You have the report that we marked as 5 Exhibit 1, sir? 6 A. Yes. 7 Q. All right. 8 Is that your signature that appears 9 on the first page of that report? 10 A. Yes. 11 Q. Did you prepare this report? 12 A. Yes. 13 Q. Is it the product of your work? 14 A. Yes. 15 Q. Did anyone assist you in the 16 preparation of this report? 17 MR. SLATER: Clem, objection. 18 Are you trying to get into areas that 19 are obviously covered by work product 20 privilege? I mean, the preparation of the 21 report is work product. Drafts are the not 22 discoverable, so I'm not sure where we're 23 going with this. 24 MR. TRISCHLER: I didn't ask about 25 drafts. I asked if anyone helped him with</p>
<p style="text-align: right;">Page 18</p> <p>1 Q. Who initially retained you? 2 A. Mr. Slater. 3 Q. When you were retained by Mr. Slater, 4 were you asked to analyze data and provide an 5 opinion on whether levels of NDMA and NDEA 6 observed in valsartan-containing medication was 7 capable of causing cancer in humans? 8 A. Yes. 9 Q. Did you attempt to answer that 10 question in the July 6, 2021 report that's been 11 filed in this case? 12 A. Yes. 13 MR. TRISCHLER: I'm going to mark as 14 Exhibit 1 to the deposition a copy of your 15 July 6th, 2021 report. 16 (Whereupon, Exhibit 1 was marked for 17 identification.) 18 Q. Do you have that with you, Dr. Hecht. 19 A. Yes, I do. 20 THE VIDEOGRAPHER: Counsel, would you 21 like me to pull that up on the screen? 22 MR. TRISCHLER: If need be. It 23 might -- let's -- 24 MR. SLATER: He has it in hard copy, 25 I think.</p>	<p style="text-align: right;">Page 20</p> <p>1 the report. It could have been his wife, it 2 could have been an associate professor. It 3 could have been anyone, Adam. 4 MR. SLATER: So anyone other than a 5 lawyer? 6 I'll allow him to answer. 7 Q. Did anyone assist you in the 8 preparation of this report, sir? 9 A. Yes. I was assisted by Mr. Slater. 10 Q. I'm not interested in what assistance 11 Mr. Slater may have provided, so other than 12 Mr. Slater, did anyone assist you in the 13 preparation of this report? 14 A. No. 15 Q. Did anyone write any sections of this 16 report for you? 17 A. No. 18 Q. In the conclusion to your report that 19 appears on page 27, you write "These nitrosamines 20 in valsartan-containing medication posed an 21 unacceptable risks of causing or substantially 22 contributing to the causation of cancer for those 23 ingesting the valsartan." 24 Did I read that correctly? 25 A. Presumably.</p>

<p style="text-align: right;">Page 21</p> <p>1 Q. Is there a difference in your mind 2 between an exposure that creates an unacceptable 3 risk of contributing to cancer causation and an 4 exposure that definitely causes cancer? 5 MR. SLATER: Objection to the form of 6 the question. 7 You can answer. 8 A. Repeat the question. 9 Q. Sure. 10 Is there a difference in your mind 11 between an exposure that creates an unacceptable 12 risk of contributing to cancer causation and an 13 exposure that definitely causes cancer? 14 MR. SLATER: Same objection. 15 You can answer. 16 A. Yes. 17 Q. What's the difference in your mind? 18 MR. SLATER: Same objection. 19 You can answer. 20 A. We are using the available data to 21 determine whether it's probable or even likely 22 that certain exposure could cause cancer versus 23 another situation where we know perhaps a person 24 has been treated with a chemotherapeutic drug that 25 has carcinogenic side effects where you know on an</p>	<p style="text-align: right;">Page 23</p> <p>1 reasonable certainty. 2 Q. Well, expert opinions -- strike that. 3 Expert witnesses in civil litigation 4 of this nature are supposed to provide scientific 5 testimony to a reasonable degree of scientific 6 certainty. 7 Is that your intention today? 8 A. Yes. 9 Q. So to a reasonable degree of 10 scientific certainty, what I'm asking you is are 11 there instances where we can definitively 12 determine the cause of cancer and instances where 13 we could not? 14 MR. SLATER: Objection. 15 You can answer. 16 A. Yes, there are instances where we can 17 definitively determine the cause of cancer. 18 Q. So what I'm trying to understand, 19 sir, is the opinion that you intend to offer in 20 this case. 21 Did NDMA and NDEA in 22 valsartan-containing medications increase the risk 23 of cancer or do you intend to offer the opinion 24 that small amounts of nitrosamines observed in the 25 valsartan-containing medications definitively</p>
<p style="text-align: right;">Page 22</p> <p>1 individual basis that you know the 2 chemotherapeutic drug caused perhaps a second 3 cancer, a different cancer than the one the person 4 was being treated for. 5 I don't know. Does that answer your 6 question? 7 Q. I'm not sure. 8 A. So in this particular case, we don't 9 know about the individual exposure and outcome. 10 All we know about is that the valsartan drug 11 contained a carcinogen. Whereas in the other case 12 that you mentioned, I believe what you were saying 13 is we know if we administer a certain cancer 14 causing agent to a given person and that person 15 gets cancer, then we know cause and effect in that 16 individual. 17 Is that your question? 18 Q. I'm not sure that was my question, 19 but I think what I heard you say is that in some 20 instances, we can tell cause and effect with 21 reasonable certainty and some instances, we 22 cannot? 23 MR. SLATER: Objection. 24 You can answer. 25 A. I don't know what you mean by</p>	<p style="text-align: right;">Page 24</p> <p>1 caused cancer? 2 MR. SLATER: Objection. 3 Multiple reasons. 4 You can answer, Dr. Hecht. 5 A. They increased the risk of cancer. 6 Q. Now, there are lots of risk factors 7 for cancer; true? 8 A. Yes. 9 Q. Old age is a risk factor, correct? 10 A. Yes. 11 Q. People over the age of 50 are at an 12 increased risk of cancer; true? 13 A. Correct. 14 Q. People over the age of 50 are at an 15 increased risk of cancer regardless whether they 16 take valsartan; true? 17 A. Yes. 18 Q. People over the age of 50 are at an 19 increased risk of cancer regardless of whether 20 they took valsartan containing small amounts of 21 nitrosamines; true? 22 MR. SLATER: Objection. 23 You can answer. 24 A. Yes. 25 MR. SLATER: Dr. Hecht, one second.</p>

<p style="text-align: right;">Page 25</p> <p>1 Just give a pause because he's going pretty 2 quick and I need to have a little time to 3 place my form objections to the questions and 4 then I would expect I'll go ahead and say you 5 could answer every time or virtually every 6 time, but just give a little pause so I don't 7 step on your answer. 8 Okay? 9 THE WITNESS: Okay. 10 Q. That's fair, Dr. Hecht. I probably 11 should have told you at the beginning, that 12 especially taking these depositions remotely, we 13 have to be careful not all to speak at the same 14 time because if you and I or Adam and I are 15 speaking at the same time, the audio tends to go 16 out and the court reporter can't take everything 17 down. If you could try to pause before -- after I 18 finish my question, give Adam a chance to 19 interject if he needs to, that will make things go 20 a lot more smoothly. My fault for not covering. 21 Okay? 22 A. Okay. 23 Q. So is a family history of cancer also 24 a risk factor for cancer? 25 A. Yes.</p>	<p style="text-align: right;">Page 27</p> <p>1 duration of exposure? 2 A. Yes. 3 Q. And -- 4 MR. SLATER: Belated objection. 5 It went a little quick, but you could 6 continue. 7 Q. The reason I thought we could agree 8 on that is you seemed to acknowledge that fact in 9 the conclusion of your report on page 27 when you 10 write that any increased risk would be 11 commensurate with the impurity level, the dose and 12 the period of use. 13 Is that right? 14 A. Yes. 15 Q. Are you familiar with the old adage 16 that "The dose makes the poison"? 17 A. Yes. 18 Q. Do you agree with that statement? 19 A. Yes. 20 Q. All substances -- strike that. 21 Virtually all substances known to man 22 have a capacity to be toxic at some level; true? 23 MR. SLATER: Objection. 24 You can answer. 25 A. All substances known to man? I don't</p>
<p style="text-align: right;">Page 26</p> <p>1 Q. Is tobacco use a risk factor for 2 cancer? 3 A. Yes. 4 Q. Is alcohol use a risk factor for 5 cancer? 6 A. Yes. 7 Q. Is obesity a risk factor for cancer? 8 A. Yes. 9 Q. What you are saying here today or 10 what your opinion that you intend to offer in this 11 case is is that increased nitrosamine intake is 12 also a risk factor for cancer, you believe? 13 A. Yes. 14 Q. I assume we could also agree right 15 off the bat, Dr. Hecht, that just because 16 something is a risk factor doesn't mean that it 17 caused cancer? 18 A. Correct. 19 Q. You can be 400 pounds, but that 20 doesn't mean that's the reason why you develop 21 lung cancer; true? 22 A. Correct. 23 Q. Do you also understand and can we 24 agree that the question of whether a substance is 25 capable of causing cancer is dependent on dose and</p>	<p style="text-align: right;">Page 28</p> <p>1 know about that. 2 Q. Well, let me give you a for instance. 3 Water is a life-sustaining substance, 4 correct? 5 A. Yes. 6 Q. However, water can be deadly when 7 it's consumed to excess; true? 8 A. Yes. 9 Q. So there are -- you didn't want to 10 agree with virtually all, but there are many 11 substances that have the capacity to be harmful at 12 some level; true? 13 A. Yes. 14 Q. And since there are many substances 15 that have the capacity to be harmful at some 16 level, looking at exposure levels, dose and 17 duration would be a reasonable and necessary 18 approach when evaluating cancer causation; agreed? 19 A. Yes. 20 Q. The question in this litigation to be 21 answered is not whether nitrosamines can cause 22 harm at any level. 23 Do you understand the question that 24 we're interested in getting at is whether there's 25 credible scientific evidence that the small</p>

<p style="text-align: right;">Page 29</p> <p>1 amounts of NDMA that was contained in 2 valsartan-containing medications can cause cancer 3 in humans. 4 Can we agree on that? 5 MR. SLATER: Objection to the form of 6 the question. 7 You can answer. 8 A. Yes. 9 Q. I guess a second question to be 10 answered is whether small tiny amounts of NDEA 11 found in valsartan-containing medications can 12 cause cancer in humans, right? 13 MR. SLATER: Objection to the form of 14 the question. 15 You can answer. 16 A. Yes. 17 Q. Since we can agree on the questions 18 to be answered, I take it that what the reason 19 that you're here is that you were retained by 20 Mr. Slater and the lawyers and the plaintiff group 21 to help analyze and provide answers to those two 22 questions. 23 Is that accurate? 24 MR. SLATER: Objection. 25 You can answer.</p>	<p style="text-align: right;">Page 31</p> <p>1 data on nitrosamine levels in valsartan products 2 from some manufacturers, correct? 3 MR. SLATER: Objection. 4 Mischaracterization of the testimony. 5 You can answer. 6 A. Yes. I looked at what's in the 7 literature and what's in the documents that I was 8 given. 9 Q. Okay. 10 So again, I'm just looking for broad 11 strokes in terms of what work you did to sit down 12 and write this report that we marked as Exhibit 1. 13 You've told me looking at literature 14 and looking at documents and I assume we're 15 talking about company documents that were provided 16 to you by Mr. Slater and his team, right? 17 A. Yes, in part. And also published 18 literature like the EMA report. 19 Q. Okay. 20 A. Other publications in the open 21 literature that have discussed this. 22 Q. Okay. 23 My apologies for interrupting you 24 there briefly. 25 Other than looking at the literature</p>
<p style="text-align: right;">Page 30</p> <p>1 A. Yes. 2 Q. So in broad strokes, Dr. Hecht, tell 3 me generally what work you did to answer those two 4 questions. 5 MR. SLATER: Objection. 6 You can answer. 7 A. Well, I looked to the literature and 8 all of the data regarding the contamination of 9 valsartan with dimethylnitrosamine, 10 dimethylnitrosamine. My conclusion was that it 11 posed -- that it should not have been there, first 12 of all, and it posed an unacceptable risk to 13 people using these medications. 14 Q. Let me stop you. It sounds like you 15 were finished anyway, Dr. Hecht. If my question 16 was unclear, I apologize. I wasn't really 17 interested in getting at all of your opinions 18 right now. 19 My question was if you could just 20 tell me in a general fashion what work you did to 21 answer the questions or to form your opinions. 22 You told me that so far you looked up 23 literature, correct? 24 A. Yes. 25 Q. You told me that you looked at some</p>	<p style="text-align: right;">Page 32</p> <p>1 and documents that were provided to you by 2 Mr. Slater and his team, is there anything else 3 you did to sit down and write the report that we 4 marked as Exhibit 1? 5 MR. SLATER: Objection. 6 You can answer. 7 A. Anything else that I did? I, you 8 know, depended on my experience and knowledge of 9 the literature about nitrosamine carcinogenesis. 10 So I depended on that knowledge, I drew on it to 11 write the report. 12 Q. Sure. 13 Now, I understand -- and I'm going to 14 get into your background in a little bit -- but I 15 understand you drew upon and relied upon your 16 background in reaching conclusions based on your 17 review of the literature and review of the 18 documents provided to you by Mr. Slater. 19 That's what you're telling me, 20 correct? 21 A. Yes. 22 Q. Was there any other work that you 23 actively did to prepare the report other than what 24 we've described? 25 A. I'm not sure exactly what you mean by</p>

<p style="text-align: right;">Page 33</p> <p>1 other -- I wrote the report based on the sources 2 that I had. 3 (Whereupon, Exhibit 2 was marked for 4 identification.) 5 Q. So let's -- let me ask you some 6 questions about your background then. 7 I have attached as Exhibit 2 a copy 8 of your CV, which contains a rather large 9 bibliography. 10 Do you happen to have a copy of your 11 CV with you, Dr. Hecht? 12 A. It's on my computer. I don't have -- 13 MR. SLATER: It's also attached to 14 the report, Doctor. Or it should be. 15 Q. Well, if you need to refer to it to 16 answer my questions, feel free. 17 Okay? 18 A. Okay. 19 Q. But does the -- can you tell me 20 whether the CV that we've marked as Exhibit 2 and 21 which is attached to your report contains an 22 accurate list of your professional qualifications? 23 A. Yes. 24 Q. Is it complete and up to date as far 25 as you know?</p>	<p style="text-align: right;">Page 35</p> <p>1 photolysis of phenoxy compounds. 2 Q. Sounds rivetting. 3 A. Yes. 4 Q. That was a poor attempt at humor. 5 A. Yes, I know. 6 Q. Did your thesis touch on 7 nitrosamines? 8 A. No. 9 Q. May I ask your age, sir? 10 A. Seventy-eight. 11 Q. You mentioned earlier when I asked 12 you your occupation, you indicated you're a 13 professor, so currently you're in academia, right? 14 A. Correct. 15 Q. Are you an employee of the University 16 of Minnesota? 17 A. Yes. 18 Q. And so you draw a salary from the 19 university; is that right? 20 A. Yes. 21 Q. According to the CV, you're a 22 professor in the Department of Laboratory Medicine 23 and Pathology. 24 A. Correct. 25 Q. To be clear, though, you were not a</p>
<p style="text-align: right;">Page 34</p> <p>1 A. Yes. 2 Q. Is there anything that you'd like to 3 add or remove from the CV? 4 A. No. 5 Q. Based on my review of your CV, it 6 appears your formal education is in the field of 7 chemistry; is that true? 8 A. Yes. 9 Q. You have a bachelor's degree in 10 chemistry from Duke University; true? 11 A. Correct. 12 Q. And a PhD in organic chemistry that 13 you obtained in 1968, correct? 14 A. Right. 15 Q. Did you have to write a thesis to 16 obtain that PhD? 17 A. Yes. 18 Q. What was the subject matter of your 19 thesis? 20 A. The thesis was divided into two 21 parts. The first part had to do with transannular 22 carbene reactions. I'm not sure if you want me to 23 go into detail about that. 24 Q. That's all right. 25 A. The second part dealt with the</p>	<p style="text-align: right;">Page 36</p> <p>1 pathologist; agreed? 2 A. Yes. 3 Q. Are you a medical doctor? 4 A. No. 5 Q. Since you're not a medical doctor, I 6 take it you do not diagnose cancer in patients, 7 correct? 8 A. Correct. 9 Q. Have you ever diagnosed a patient 10 with esophageal cancer? 11 A. No. 12 Q. Have you ever diagnosed a patient 13 with colorectal cancer? 14 A. No. 15 MR. TRISCHLER: I'm going to mark as 16 Exhibit 3 a document that's entitled 17 "Plaintiffs' Disclosure of Cancer Types." 18 To our technician, this is one you 19 can put up on the screen for me. 20 (Whereupon, Exhibit 3 was marked for 21 identification.) 22 Q. Are you able to see that document, 23 Dr. Hecht? 24 A. Maybe you could make it a little 25 larger.</p>

<p style="text-align: right;">Page 37</p> <p>1 Q. I can't, but there's --</p> <p>2 THE VIDEOGRAPHER: Is there a</p> <p>3 specific section you'd like me to blow up?</p> <p>4 MR. TRISCHLER: Just the text in the</p> <p>5 middle.</p> <p>6 THE WITNESS: Okay.</p> <p>7 Q. Have you ever seen this document</p> <p>8 before, sir?</p> <p>9 A. Let me just read it first.</p> <p>10 Okay?</p> <p>11 Q. Sure.</p> <p>12 (Witness reviews document)</p> <p>13 A. No, I've not.</p> <p>14 Q. I'll represent to you that this is a</p> <p>15 disclosure that was filed by the plaintiffs in</p> <p>16 this litigation. It's a list of cancer types that</p> <p>17 have been placed at issue in this litigation.</p> <p>18 Okay?</p> <p>19 A. Okay.</p> <p>20 Q. Take a look.</p> <p>21 Do you see there are 13 cancer types</p> <p>22 listed? Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. Have you ever diagnosed any of these</p> <p>25 cancer types in any patient?</p>	<p style="text-align: right;">Page 39</p> <p>1 weren't medical students.</p> <p>2 Q. Was it a graduate level course in</p> <p>3 some --</p> <p>4 A. In carcinogenesis. The students came</p> <p>5 from different programs in the university, but</p> <p>6 there weren't medical students. There were</p> <p>7 graduate students in medicinal chemistry or from</p> <p>8 the St. Paul campus on nutrition.</p> <p>9 Q. Thank you.</p> <p>10 I'm trying to get an understanding</p> <p>11 was it a class that was offered by the Department</p> <p>12 of Chemistry, the Department of Biology. Help me</p> <p>13 understand that, if you can.</p> <p>14 A. No, it was a graduate course in --</p> <p>15 actually, I've forgotten exactly which division it</p> <p>16 was listed in. I don't recall whether it was</p> <p>17 medicinal chemistry or whether it was in the C</p> <p>18 fans, the food and nutrition. I'm sorry. I don't</p> <p>19 remember.</p> <p>20 Q. That's okay. It's been ten years --</p> <p>21 I understand it's been ten years since you offered</p> <p>22 the course, correct, or taught the course?</p> <p>23 A. Yes.</p> <p>24 Q. Has it been ten years since you've</p> <p>25 been in the classroom at Minnesota?</p>
<p style="text-align: right;">Page 38</p> <p>1 A. No.</p> <p>2 Q. Have you ever treated a cancer</p> <p>3 patient?</p> <p>4 A. No.</p> <p>5 Q. Going back to your role at the</p> <p>6 University of Minnesota, are you actively teaching</p> <p>7 at the moment?</p> <p>8 A. No.</p> <p>9 Q. Are you going to be teaching any</p> <p>10 courses in the 2021/2022 academic year?</p> <p>11 A. No.</p> <p>12 Q. When was the last time you taught a</p> <p>13 graduate level course?</p> <p>14 A. That's about ten years ago.</p> <p>15 Q. What was the course you taught some</p> <p>16 ten years ago?</p> <p>17 A. Chemical carcinogenesis.</p> <p>18 Q. Did you use a textbook for that</p> <p>19 course?</p> <p>20 A. No. We used the current literature.</p> <p>21 Q. Who were you teaching that graduate</p> <p>22 level course to? Was it medical students at the</p> <p>23 medical school or was it in some other</p> <p>24 environment?</p> <p>25 A. It was a mixture that -- there</p>	<p style="text-align: right;">Page 40</p> <p>1 A. Yes.</p> <p>2 Q. Have you ever taught an undergraduate</p> <p>3 course at the University of Minnesota?</p> <p>4 A. No.</p> <p>5 Q. Are you a full-time employee at this</p> <p>6 point or have you slowed down?</p> <p>7 A. No, I'm a full-time employee.</p> <p>8 MR. TRISCHLER: You can remove that</p> <p>9 exhibit, sir.</p> <p>10 Thank you.</p> <p>11 Q. Are you actively involved in any</p> <p>12 research projects at the moment?</p> <p>13 A. Yes, I am.</p> <p>14 Q. I think in your report that's marked</p> <p>15 as Exhibit 1 to this deposition you indicate at</p> <p>16 the bottom of page two that you are the principal</p> <p>17 investigator on three R01 grants --</p> <p>18 A. RO1.</p> <p>19 Q. Correct?</p> <p>20 A. Yes.</p> <p>21 Q. By the way, the Masonic Cancer Center</p> <p>22 is designated as a comprehensive cancer center,</p> <p>23 correct?</p> <p>24 A. Correct.</p> <p>25 Q. I think that's a designation given by</p>

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<p>1 the National Cancer Institute?</p> <p>2 A. Correct.</p> <p>3 Q. And Masonic would be one of over 50</p> <p>4 hospital systems over the country that have been</p> <p>5 so designated, right?</p> <p>6 A. About 50, yeah.</p> <p>7 Q. The National Cancer Institute has</p> <p>8 also designated seven laboratory centers across</p> <p>9 the country that do cutting edge cancer-related</p> <p>10 research, correct?</p> <p>11 A. Right. Those are laboratory centers.</p> <p>12 Comprehensive center includes not only laboratory</p> <p>13 research, but also treatment.</p> <p>14 Q. But Masonic is not one of the seven</p> <p>15 laboratory cancer centers designated --</p> <p>16 A. It's a comprehensive center, which</p> <p>17 includes laboratory work.</p> <p>18 Q. Going back then to the RO1 grants,</p> <p>19 these are projects that are funded by federal</p> <p>20 grants; is that right?</p> <p>21 A. Yes.</p> <p>22 Q. To whom were the three RO1 grants</p> <p>23 that you reference in your report issued?</p> <p>24 A. Well, I'm the principal investigator,</p> <p>25 but the grants are actually issued to the</p>	<p>1 smoking.</p> <p>2 Q. Okay.</p> <p>3 Thank you for the descriptions.</p> <p>4 The third one -- the third RO1 grant</p> <p>5 you mentioned, I'm not sure if I didn't hear you</p> <p>6 or didn't understand you. You said it was a</p> <p>7 clinical trial involving what?</p> <p>8 A. Watercress.</p> <p>9 Q. Forgive my ignorance.</p> <p>10 What's watercress?</p> <p>11 A. It's a plant.</p> <p>12 Q. Okay.</p> <p>13 A. It's a common food that people use in</p> <p>14 salads. Watercress.</p> <p>15 Q. Is it carcinogenic?</p> <p>16 A. No. Not at all.</p> <p>17 Q. What does the clinical trial involve?</p> <p>18 A. So we found over the years in other</p> <p>19 studies that we've done that a compound that's</p> <p>20 present in watercress called PEITC -- or phenethyl</p> <p>21 isothiocyanate -- can prevent lung cancer in rats</p> <p>22 and mice treated with tobacco carcinogens. Based</p> <p>23 on that work, we performed a clinical trial with</p> <p>24 our colleagues here at the University of Minnesota</p> <p>25 to determine whether PEITC would have a similar</p>
Page 42	Page 44
<p>1 University of Minnesota.</p> <p>2 Q. Can you describe the subject of those</p> <p>3 three current grants?</p> <p>4 A. Yes. One of them involves the</p> <p>5 mechanisms and prevention of tobacco-induced</p> <p>6 cancer caused by a group of carcinogens in tobacco</p> <p>7 products that we discovered and have worked on for</p> <p>8 many years called tobacco specific nitrosamines.</p> <p>9 The second grant --</p> <p>10 Q. I'm sorry.</p> <p>11 Would those be NNN and NNK?</p> <p>12 A. Correct. Do you want me to go on or</p> <p>13 do you want me to --</p> <p>14 Q. Yes, please.</p> <p>15 A. The second grant has to do with the</p> <p>16 carcinogens and toxicants that are possibly</p> <p>17 omitted from e-cigarettes that are present in</p> <p>18 e-cigarette paper and could be taken up by people</p> <p>19 who use these products.</p> <p>20 The third one is a clinical trial of</p> <p>21 watercress for -- to enhance the detoxification of</p> <p>22 environmental toxicants and carcinogens.</p> <p>23 Those are the three RO1 grants. I'm</p> <p>24 also the PI of a program project grant on the</p> <p>25 ethnic differences in cancer risk due to cigarette</p>	<p>1 effect in cigarette smokers as it did in</p> <p>2 laboratory animals, whether it could therefore be</p> <p>3 used as a chemo-preventative agent in people who</p> <p>4 couldn't stop smoking because they're addicted to</p> <p>5 nicotine. This compound was able to prevent</p> <p>6 cancer in animals treated with tobacco specific</p> <p>7 nitrosamines, as I mentioned.</p> <p>8 So in this clinical trial, we found</p> <p>9 that PEITC did, in fact, decrease the metabolic</p> <p>10 activation of NNK in smokers, which was the</p> <p>11 hypothesized result. But the decrease was, while</p> <p>12 significant, was quite small.</p> <p>13 However, in the same trial, we found</p> <p>14 that certain people who took the PEITC had a great</p> <p>15 increase in their ability to detoxify</p> <p>16 environmental toxicants like benzene. This formed</p> <p>17 the basis for the watercress study because</p> <p>18 watercress is a great source of PEITC. Just a</p> <p>19 salad-sized portion of watercress will, when you</p> <p>20 eat it, when you chew it, will release 20 to</p> <p>21 30 milligrams of PEITC, which was similar to the</p> <p>22 dose of the pure compound we had used in the study</p> <p>23 that I described.</p> <p>24 So that's what gave rise to the</p> <p>25 watercress trial.</p>

<p style="text-align: right;">Page 45</p> <p>1 Q. All right. I understand what you're 2 doing now in that study. I appreciate the 3 details. 4 So you've now told me about your 5 current RO1 grants and your -- 6 A. Grant project. 7 Q. -- correct. 8 A. Yes. 9 Q. Do any of your current RO1 grants or 10 the program project grant deal specifically with 11 NDMA or NDEA? 12 A. The one on tobacco specific 13 nitrosamines, while the specific names aren't 14 dealing specifically with NDMA, it's closely 15 related to NNK in terms of its mechanistic 16 properties. 17 So the answer -- the short answer to 18 your question is no, but the longer answer is that 19 yes, it's closely related. 20 Q. Well, I understand that NDMA and NNN 21 or NNK might be chemically related, but my 22 question was are these grants dealing specifically 23 with NDMA or NDEA grant research? 24 A. Not specifically. Not in the 25 specific names.</p>	<p style="text-align: right;">Page 47</p> <p>1 of that study, correct? 2 A. Yes. 3 Q. And I think it was an animal study 4 involving rats; is that right? 5 A. Yes. 6 Q. Have you ever been involved in your 7 career in any federally-funded research projects 8 involving the carcinogenicity of NDEA? 9 A. Not specifically. 10 Q. Have you ever been involved in any 11 research projects that focused on the human body's 12 metabolism of NDEA? 13 A. Human NDMA? No, not directly. 14 Q. Have you ever been involved in any 15 research projects that focused on the human body's 16 metabolism of NDEA? 17 A. Not directly, no. 18 Q. Have you ever been involved in any 19 research projects devoted to analyzing the 20 mechanisms of action of cancer induction from 21 NDMA? 22 A. Yes. 23 Q. Would that be the same study that you 24 told me about before, the rat comparison to NNK? 25 A. That was one, yes.</p>
<p style="text-align: right;">Page 46</p> <p>1 Q. Have you ever been involved in any 2 federally-funded research products dealing 3 directly with the carcinogenicity of NDMA? 4 A. Yes. 5 Q. Can you tell me about those, please? 6 A. Well, when I was still at the 7 American Health Foundation, we did studies that 8 compared the carcinogenicity and metabolism of 9 NDMA and NNK. We did this because NNK was a 10 relatively -- a relatively new carcinogen that 11 hadn't been explored with a regard to its 12 carcinogenic properties and mechanisms of action, 13 whereas NDMA has been known as a carcinogen since 14 1956. 15 So since NDMA was such a 16 well-established carcinogen, we thought it would 17 be important to compare some of the properties of 18 NNK and NDMA, so we did do those studies. 19 Q. I think that was back in the 1980s, 20 you said? 21 A. Yes. 22 Q. It was a comparative analysis of the 23 potency of NDMA to NNK? 24 A. Yes. 25 Q. You published the results of those --</p>	<p style="text-align: right;">Page 48</p> <p>1 Q. Have you ever been involved in any 2 research projects devoted to analyzing the 3 mechanism of action of cancer induction from NDEA? 4 A. Not directly. 5 Q. Since you don't have a medical 6 degree, I take it you're not Board Certified in 7 oncology, radiology or any other medical 8 discipline, right? 9 A. Correct. 10 Q. Are you an expert in the field of 11 epidemiology? 12 A. I have worked with epidemiologists 13 throughout my career, yes. 14 Q. I have, too. Does that make me an 15 expert in epidemiology? 16 MR. SLATER: Objection to the form. 17 You can answer. 18 A. I don't know. I don't know if you're 19 an expert in epidemiology. 20 Q. Do you hold yourself out as an expert 21 in the field of epidemiology? 22 A. That depends on your definition of 23 the word "expert." 24 Q. Do you agree that epidemiology is the 25 study of the distribution and determinants of a</p>

<p style="text-align: right;">Page 49</p> <p>1 disease in a population?</p> <p>2 A. Yes.</p> <p>3 Q. Do you have a degree in epidemiology?</p> <p>4 A. No.</p> <p>5 Q. Are you Board Certified in the field</p> <p>6 of epidemiology?</p> <p>7 A. No.</p> <p>8 Q. Are you a pharmacoepidemiologist?</p> <p>9 A. Pardon me?</p> <p>10 Q. Are you a pharmacoepidemiologist?</p> <p>11 A. No.</p> <p>12 Q. Do you have a degree in pharmacology?</p> <p>13 A. No.</p> <p>14 Q. Do you agree that pharmacology is the</p> <p>15 study of effects of drugs on a population?</p> <p>16 A. Yes.</p> <p>17 Q. Have you ever been trained or</p> <p>18 employed as a clinical pharmacologist?</p> <p>19 A. No.</p> <p>20 Q. Are you a molecular biologist?</p> <p>21 A. No.</p> <p>22 Q. On your CV and also in response to</p> <p>23 one of my earlier questions, you mentioned you</p> <p>24 were affiliated for a time with the American</p> <p>25 Health Foundation.</p>	<p style="text-align: right;">Page 51</p> <p>1 is that right?</p> <p>2 A. Yes.</p> <p>3 Q. Were you in charge of all the</p> <p>4 foundation's research activities during that</p> <p>5 nine-year period?</p> <p>6 A. That depends what you mean by "in</p> <p>7 charge of." I was responsible for overseeing and</p> <p>8 coordinating the research. It was up to the</p> <p>9 individual investigators to get the research</p> <p>10 funded. My role was to bring people together to</p> <p>11 look for opportunities for interdisciplinary</p> <p>12 collaboration and also to write the cancer center</p> <p>13 grant application from the foundation to the</p> <p>14 National Cancer Institute.</p> <p>15 Q. The vast majority of the funding of</p> <p>16 the American Health Foundation came from federal</p> <p>17 grants and contracts awarded through NCI, correct?</p> <p>18 A. Correct.</p> <p>19 Q. So you would have to write the grant</p> <p>20 applications to outline the scientific basis for</p> <p>21 the research that you wanted to conduct so that</p> <p>22 you could get those federal funds into the</p> <p>23 facility to do that work?</p> <p>24 A. Yes. That's true, but each</p> <p>25 individual principal investigator was responsible</p>
<p style="text-align: right;">Page 50</p> <p>1 Is that right?</p> <p>2 A. I worked there for 23 years.</p> <p>3 Q. That was before you moved to the</p> <p>4 University of Minnesota, right?</p> <p>5 A. Correct.</p> <p>6 Q. Why did you leave the American Health</p> <p>7 Foundation?</p> <p>8 A. I was concerned about the future of</p> <p>9 the foundation and also I had a very nice offer</p> <p>10 from the University of Minnesota.</p> <p>11 Q. Nice offer from who?</p> <p>12 A. The University of Minnesota.</p> <p>13 Q. I'm sorry. Sometimes I don't hear</p> <p>14 great and sometimes with the computer your voice</p> <p>15 trails off a little bit, Doctor. If I ask you to</p> <p>16 repeat yourself, it's just because I couldn't hear</p> <p>17 the answer.</p> <p>18 Okay?</p> <p>19 A. Okay. Sure.</p> <p>20 The offer was from the University of</p> <p>21 Minnesota. The cancer center in particular.</p> <p>22 Q. Understood.</p> <p>23 When you were at the American Health</p> <p>24 Foundation, according to your CV, you held the</p> <p>25 title of Director of Research for over nine years;</p>	<p style="text-align: right;">Page 52</p> <p>1 for -- also responsible for funding their own</p> <p>2 research through grants and contracts mostly from</p> <p>3 the National Cancer Institute.</p> <p>4 Q. To whom did you report in your role</p> <p>5 as Director of Research when you were at the</p> <p>6 American Health Foundation?</p> <p>7 A. To Ernst Wynder, president and</p> <p>8 founder of the foundation.</p> <p>9 Q. At some point in time, the American</p> <p>10 Health Foundation changed its name to the</p> <p>11 Institute for Cancer Prevention, right?</p> <p>12 A. That was just The Institute. So the</p> <p>13 foundation included two branches. There was a</p> <p>14 branch in New York City, which focused on</p> <p>15 epidemiology. That was Dr. Wynder's specialty.</p> <p>16 You may be aware that he was the first to -- in</p> <p>17 this country -- to establish the relationship</p> <p>18 between smoking and lung cancer.</p> <p>19 Then there was The Institute, which</p> <p>20 was in Westchester County, which was the basic</p> <p>21 research, the laboratory research part of the</p> <p>22 foundation. My role was Director of Research of</p> <p>23 the laboratory part of the foundation.</p> <p>24 Q. I understand.</p> <p>25 The foundation, though, changed its</p>

<p style="text-align: right;">Page 53</p> <p>1 name to the Institute for Cancer Prevention, 2 right? 3 A. No. The foundation never changed its 4 name. It's the Naylor Dana Institute, which is 5 the basic research institute. It changed its name 6 to Institute for Cancer Prevention. That was 7 after I left. 8 Q. Where is the health foundation today? 9 A. It went out of business in the late 10 90s. 11 Q. It's out of business just as the IFC 12 is out of business, right? 13 A. Yes. 14 Q. They filed for bankruptcy, right? 15 A. I believe. Something like that. I 16 don't really know the details. 17 Q. Several of the leaders of that 18 organization were indicted on federal charges, 19 right? 20 A. There were some problems, yes. This 21 was all after I left. Well after I left. 22 Q. The leaders of the American Health 23 Foundation and IFCP were indicted on charges of 24 improperly diverting and misusing federal funds 25 for cancer research, right?</p>	<p style="text-align: right;">Page 55</p> <p>1 allegations that were brought by the federal 2 government involving misuse of funds at IFCP and 3 AHF predate your departure from the organization? 4 A. I really don't know. 5 Q. You don't remember hearing anything 6 about any of that while you were there? 7 A. No. 8 Q. You said earlier that you were 9 concerned about the future of the organization, 10 which is one of the reasons why you left. 11 A. Yes. 12 Q. Did your concern have something to do 13 with the federal charges and federal 14 investigations that were going on? 15 A. Not at all. 16 Q. Why were you concerned about the 17 future of the organization when you were there? 18 A. Ernst Wynder's management style 19 about, you know, the allocation of resources 20 within the institute. It had nothing to do with 21 any of the things you're talking about. 22 Q. The things I'm talking about actually 23 happened. 24 You know that, right? 25 MR. SLATER: Objection.</p>
<p style="text-align: right;">Page 54</p> <p>1 A. Something like that, yes. 2 Q. Several of the members of the 3 management group, including the CFO, pled guilty 4 to those charges, right? 5 A. I guess so. 6 Q. Were any charges ever brought against 7 you? 8 A. No. 9 Q. Were you ever interviewed or 10 investigated by the FBI in connection with AHF and 11 IFCP's misuse of federal funds? 12 A. No. 13 Q. In addition to the criminal matters, 14 there were also a lot of civil charges that were 15 brought by the United States Department of Justice 16 against your old employer and its employees, 17 right? 18 A. I really don't know anything about 19 that. 20 Q. Were any charges -- civil charges -- 21 brought against you from your work at -- 22 A. No. 23 Q. -- AHF? 24 A. No. 25 Q. Isn't it true that many of the</p>	<p style="text-align: right;">Page 56</p> <p>1 Is this an argument now that you'd 2 like to start with Dr. Hecht or do you have 3 another question? 4 MR. TRISCHLER: I thought I did ask a 5 question, Adam. 6 MR. SLATER: I took it as 7 argumentative and I object to it. 8 You can answer, but I'm sure he's 9 going to -- Mr. Trischler will start asking 10 direct questions instead of what just 11 happened. 12 A. What was the question again? 13 Q. There were federal investigations, 14 federal indictments and federal charges of fraud 15 against AHF, IFCP and its employees for misuse of 16 federal funds. 17 You are aware of that; true? 18 A. I heard about it. 19 Q. And at the time that you were 20 Director of Research, isn't it true that AHF 21 settled a federal lawsuit by paying the government 22 millions of dollars to replace and reimburse the 23 government for misuse of federal grant monies? 24 A. I don't know. I don't think that 25 happened when I was there. It may have. I don't</p>

<p style="text-align: right;">Page 57</p> <p>1 know. I honestly don't know.</p> <p>2 Q. Were you ever deposed in connection</p> <p>3 with any of those lawsuits?</p> <p>4 A. No.</p> <p>5 Q. Did you ever given sworn testimony in</p> <p>6 connection with any of those lawsuits?</p> <p>7 A. No.</p> <p>8 Q. Was the scrutiny from the federal</p> <p>9 authorities and investigators anything that led to</p> <p>10 your departure from that company and your decision</p> <p>11 to head to the University of Minnesota?</p> <p>12 A. No, not at all.</p> <p>13 Q. In your report that I have marked as</p> <p>14 Exhibit 1, you indicated that you've been involved</p> <p>15 in the -- in research relating to nitrosamine</p> <p>16 since 1973.</p> <p>17 A. Correct.</p> <p>18 Q. That's true?</p> <p>19 A. Yes.</p> <p>20 Q. How many different nitrosamines have</p> <p>21 been identified by the scientific community?</p> <p>22 A. How many have been identified?</p> <p>23 Q. Yes, sir.</p> <p>24 A. Do you mean in connection with cancer</p> <p>25 or --</p>	<p style="text-align: right;">Page 59</p> <p>1 Q. Total number of nitrosamines that</p> <p>2 have been identified.</p> <p>3 A. Independent of any biological</p> <p>4 activity?</p> <p>5 Q. Yes.</p> <p>6 A. In all the chemical literature?</p> <p>7 Q. Yes.</p> <p>8 A. I'm guessing between 100 and 200.</p> <p>9 Q. I've seen research suggesting there's</p> <p>10 been as many as 300 nitrosamines identified.</p> <p>11 Would you dispute that?</p> <p>12 A. That's possible, sure. Nitrosamines</p> <p>13 or nitroso compounds?</p> <p>14 Q. Nitrosamines.</p> <p>15 A. You're sure of that?</p> <p>16 Q. So if we just use the number 300,</p> <p>17 while the scientific community has identified</p> <p>18 around 300 different nitrosamines, is it true that</p> <p>19 most of your research has focused on nitrosamines</p> <p>20 found in tobacco products?</p> <p>21 A. Yes.</p> <p>22 Q. For instance, you've told us here</p> <p>23 today that you continue to work on and do</p> <p>24 important research on tobacco-related nitrosamines</p> <p>25 like NNK and NNN?</p>
<p style="text-align: right;">Page 58</p> <p>1 Q. No.</p> <p>2 A. -- just in general? I mean, you</p> <p>3 know, there's an infinite number of possible</p> <p>4 nitrosamines that can be synthesized and</p> <p>5 identified. The actual number that have actually</p> <p>6 been identified by chemists, it's probably in the</p> <p>7 hundreds. I don't really know that number.</p> <p>8 Q. Okay.</p> <p>9 A. They're not all -- wouldn't all be</p> <p>10 with respect to cancer research. I mean</p> <p>11 nitrosamines have been known as a class --</p> <p>12 chemical class long before they were known to be</p> <p>13 carcinogenic.</p> <p>14 Q. I appreciate all that information and</p> <p>15 I understand that there may be nitrosamines that</p> <p>16 can be synthesized that have yet to be identified.</p> <p>17 I was just asking if you know generally from your</p> <p>18 involvement in this field how many have been</p> <p>19 identified both as carcinogenic and</p> <p>20 noncarcinogenic.</p> <p>21 What you told me is that the number</p> <p>22 is in the hundreds, right?</p> <p>23 A. Yeah. As carcinogenic?</p> <p>24 Q. No. That wasn't my question.</p> <p>25 A. Okay. What's your question?</p>	<p style="text-align: right;">Page 60</p> <p>1 A. Yes.</p> <p>2 Q. Your research was fundamentally</p> <p>3 important in identifying those nitrosamines as</p> <p>4 carcinogenic, correct?</p> <p>5 A. Yes.</p> <p>6 Q. Is NNK listed as a Class 1</p> <p>7 carcinogen?</p> <p>8 A. NNK and NNN are together considered</p> <p>9 Class 1 by IARC. They're listed together because</p> <p>10 they always occur together.</p> <p>11 Q. While most of your work and research</p> <p>12 is focused on nitrosamines contained in tobacco</p> <p>13 products, is it fair to say that you've not</p> <p>14 researched all the 300 plus nitrosamines</p> <p>15 recognized by the scientific community?</p> <p>16 A. Not all of them, no.</p> <p>17 Q. Prior to your retention in this case,</p> <p>18 had you ever published any research dealing</p> <p>19 specifically with the carcinogenicity of NDEA in</p> <p>20 humans?</p> <p>21 A. I think you asked me that before.</p> <p>22 No.</p> <p>23 Q. I asked you before whether you'd done</p> <p>24 any research. This question is whether you</p> <p>25 published --</p>

<p style="text-align: right;">Page 61</p> <p>1 A. No, not NDEA.</p> <p>2 Q. Your work, your published research</p> <p>3 with respect to NDEA related to a comparative</p> <p>4 evaluation of the toxicity of NDEA to NNK,</p> <p>5 correct?</p> <p>6 A. Correct.</p> <p>7 That was NDMA.</p> <p>8 Q. If I misspoke, I apologize. Yes.</p> <p>9 In that comparative analysis --</p> <p>10 A. Right.</p> <p>11 Q. -- toxicity was an animal study done</p> <p>12 in rats, right?</p> <p>13 A. Correct.</p> <p>14 Q. Have you ever in the course of your</p> <p>15 career prior to your retention in this case</p> <p>16 published any research dealing with the</p> <p>17 carcinogenicity of NDMA in humans?</p> <p>18 A. No.</p> <p>19 Q. Prior to your retention in this case,</p> <p>20 had you ever published any research on human DNA</p> <p>21 repair capacity when exposed to NDMA or NDEA?</p> <p>22 A. No.</p> <p>23 Q. Prior to your retention in this case,</p> <p>24 have you ever published any peer-reviewed research</p> <p>25 dealing directly with the level of the reactivity</p>	<p style="text-align: right;">Page 63</p> <p>1 Q. You've never published any research</p> <p>2 on the pharmacokinetics of NDMA or NDEA; is that</p> <p>3 true?</p> <p>4 A. Yes.</p> <p>5 Q. The CV that you provided to us which</p> <p>6 we marked as Exhibit 2 lists some major</p> <p>7 contributions to science that begin on page six.</p> <p>8 It's actually under the title "Selected</p> <p>9 Contributions to Science."</p> <p>10 Are you familiar with that --</p> <p>11 A. Yes.</p> <p>12 Q. -- in your CV?</p> <p>13 A. Yes.</p> <p>14 Q. The first one that you list there is</p> <p>15 basically the study of tobacco-specific</p> <p>16 nitrosamines and the identification of NNN and</p> <p>17 NNK, which we talked about, correct?</p> <p>18 A. Yes.</p> <p>19 Q. Then you then list the -- number two</p> <p>20 as being the application of tobacco carcinogen and</p> <p>21 toxic and biomarkers in clinical and</p> <p>22 epidemiological studies, correct?</p> <p>23 A. Correct.</p> <p>24 Q. The third thing you list under your</p> <p>25 significant contributions to science is metabolism</p>
<p style="text-align: right;">Page 62</p> <p>1 stability and DNA binding of NDMA or NDEA when</p> <p>2 exposed to -- as a result of human exposure to</p> <p>3 those chemicals?</p> <p>4 A. No.</p> <p>5 Q. Prior to this case, have you ever</p> <p>6 studied and published on the efficiency of human</p> <p>7 metabolic enzymes in metabolizing and eliminating</p> <p>8 NDMA or NDEA?</p> <p>9 MR. SLATER: Objection.</p> <p>10 You can answer.</p> <p>11 A. No.</p> <p>12 Q. Did you answer, sir? If you did, I</p> <p>13 didn't hear.</p> <p>14 A. The answer is no.</p> <p>15 Q. Are you a pharmacokineticist?</p> <p>16 A. No.</p> <p>17 Q. Do you recognize pharmacokinetics as</p> <p>18 the discipline that's involved in studying the</p> <p>19 absorption, delivery, metabolism and elimination</p> <p>20 of substances from the body?</p> <p>21 A. Yes.</p> <p>22 Q. You've never been trained in that</p> <p>23 discipline, correct?</p> <p>24 MR. SLATER: Objection.</p> <p>25 A. Correct.</p>	<p style="text-align: right;">Page 64</p> <p>1 and DNA adducts -- adducts, A-D-D-U-C-T-S, for the</p> <p>2 court reporter -- of PAH and aldehydes.</p> <p>3 Did I pronounce that correctly?</p> <p>4 A. Yes.</p> <p>5 Q. What is PAH and aldehydes? What are</p> <p>6 they?</p> <p>7 A. Polycyclic aromatic hydrocarbons.</p> <p>8 Those are carcinogens present in the environment</p> <p>9 and in tobacco smoke that form as a result of</p> <p>10 incomplete combustion of organic matter. The best</p> <p>11 known of which is benzo(a)pyrene.</p> <p>12 Aldehydes are a class of chemical</p> <p>13 compounds. The best known are formaldehyde and</p> <p>14 acid aldehyde and acrolein that are formed in</p> <p>15 human metabolism of alcohol and they're also</p> <p>16 humans are exposed through the general environment</p> <p>17 and tobacco smoke, as well as endogenous roots.</p> <p>18 Q. Okay.</p> <p>19 Then the fourth of five things that</p> <p>20 you list under your contributions to science is</p> <p>21 chemo prevention of cancer and that's -- that</p> <p>22 involves studying things that can help prevent the</p> <p>23 carcinogenic effect of exposures, correct?</p> <p>24 A. Yes.</p> <p>25 Q. Like the RO1 study involving the</p>

<p style="text-align: right;">Page 65</p> <p>1 salad we talked about?</p> <p>2 A. Watercress, yes.</p> <p>3 Q. Learn something new every day. I</p> <p>4 never knew what watercress was.</p> <p>5 A. Now you know.</p> <p>6 Q. Number five is expertise in tobacco</p> <p>7 carcinogenesis, correct?</p> <p>8 A. Yes.</p> <p>9 Q. In going through your CV and listing,</p> <p>10 you know, what your major scientific contributions</p> <p>11 have been during your long career, you don't</p> <p>12 mention anything specifically related to NDEA,</p> <p>13 true?</p> <p>14 A. Correct.</p> <p>15 Q. You don't mention anything</p> <p>16 specifically related to NDMA, correct?</p> <p>17 A. Correct.</p> <p>18 Q. Do you hold yourself out as an expert</p> <p>19 in toxicology?</p> <p>20 A. No. I'm not a toxicologist.</p> <p>21 Q. Are you a member of the Society of</p> <p>22 Toxicology?</p> <p>23 A. No. I don't think I paid my dues. I</p> <p>24 was a member, but I'm not now.</p> <p>25 MR. TRISCHLER: I'm not sure what</p>	<p style="text-align: right;">Page 67</p> <p>1 peer-reviewed scientific literature any data that</p> <p>2 would provide a toxicological assessment of human</p> <p>3 health risk from exposure to NDMA?</p> <p>4 A. Well, we published work that could</p> <p>5 contribute to that. As far as an overall</p> <p>6 toxicological evaluation, no.</p> <p>7 Q. Have you ever published an overall</p> <p>8 toxicological evaluation of NDEA?</p> <p>9 A. No.</p> <p>10 Q. You list in your bibliography about</p> <p>11 618 entries that you have been responsible for.</p> <p>12 Do you recall that?</p> <p>13 A. Yes.</p> <p>14 Q. I know that one dealt specifically</p> <p>15 with NDMA because we've already talked a little</p> <p>16 bit about it. That would be the comparative study</p> <p>17 between NDMA and NNK, right?</p> <p>18 A. Yes.</p> <p>19 MR. TRISCHLER: Why don't we just go</p> <p>20 ahead and have that -- since we've been</p> <p>21 referring to it -- that paper marked. I</p> <p>22 think we'll mark it Exhibit 4 we're up to.</p> <p>23 (Whereupon, Exhibit 4 was marked for</p> <p>24 identification.)</p> <p>25 Q. It's entitled, for the record,</p>
<p style="text-align: right;">Page 66</p> <p>1 that noise is.</p> <p>2 Can everyone mute their line, please?</p> <p>3 MR. SLATER: Someone is certainly off</p> <p>4 mute.</p> <p>5 THE VIDEOGRAPHER: I just muted them</p> <p>6 for you guys.</p> <p>7 MR. TRISCHLER: Sorry about that,</p> <p>8 Doctor.</p> <p>9 Q. Prior to your retention in this case,</p> <p>10 did you ever conduct a toxicological evaluation of</p> <p>11 human health risks from exposure to NDMA?</p> <p>12 A. No.</p> <p>13 Q. Prior to your retention in this case,</p> <p>14 had you ever conducted a toxicological evaluation</p> <p>15 of human health risk from exposure to NDEA?</p> <p>16 A. No, but I'm not sure exactly what you</p> <p>17 mean by toxicological evaluation. I mean, I've</p> <p>18 served on committees -- I do serve on a committee</p> <p>19 presently looking at nitrosamines and food and</p> <p>20 I've been on an FDA panel which talked about</p> <p>21 nitrosamine contamination of the drugs, so I'm not</p> <p>22 sure exactly what you mean by the question.</p> <p>23 Q. Let me see if I could clear it up</p> <p>24 then.</p> <p>25 Have you ever published in the</p>	<p style="text-align: right;">Page 68</p> <p>1 "Comparative Tumorigenicity of DNA Methylation in</p> <p>2 F344 Rats by Methylnitrosamino Butanone and</p> <p>3 Nitrosodimethylamine."</p> <p>4 How did I do in the pronunciations?</p> <p>5 A. Pretty bad.</p> <p>6 Q. Surprising.</p> <p>7 Do you have that paper in front of</p> <p>8 you or do you need it? If not, I could have it</p> <p>9 put up on the screen?</p> <p>10 A. I don't have it in front of me.</p> <p>11 MR. TRISCHLER: Bill, can you put it</p> <p>12 up?</p> <p>13 THE VIDEOGRAPHER: Sure.</p> <p>14 What is the name of the file? I</p> <p>15 don't see one that started with what you had</p> <p>16 announced.</p> <p>17 MR. TRISCHLER: I think the file</p> <p>18 would be Comparative Tumorigenicity --</p> <p>19 THE VIDEOGRAPHER: I'm not seeing --</p> <p>20 I'm going to scroll through. I'm going to</p> <p>21 see if it's maybe labeled something else.</p> <p>22 Yes, got it. One moment.</p> <p>23 Q. So I put up as Exhibit 4 at least the</p> <p>24 first page of your paper that we've been talking</p> <p>25 about, Dr. Hecht.</p>

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<p>1 To go through this efficiently, I'll 2 just ask questions and if you need to review or 3 consult any part of your paper to answer them, 4 please let me know that and we can take as much 5 time as you need to read the document or to review 6 a section of it. 7 Okay? 8 A. Okay. 9 Q. In this paper, as we've already 10 talked about, the purpose of it was to compare the 11 toxicity and potency of NNK to NDMA, right? 12 A. The carcinogenicity, yes. Not 13 necessarily the toxicity. 14 Q. Okay. Understood. 15 As I understand it, a group of 30 16 rats was given IV doses of NNK for 20 weeks; is 17 that right? 18 A. IV? 19 Q. Yes, that's what I said. 20 A. Sub Q I thought it was. 21 Q. Okay. There's a section marked 22 "Bioassay" on the first page there. Can you blow 23 that up for the doctor? Maybe I misread it, 24 but -- 25 A. SC. Subq. Subcutaneous injection,</p>	<p>1 MR. SLATER: It's in there now. 2 THE VIDEOGRAPHER: Great. 3 MR. SLATER: Sorry about that. 4 MR. TRISCHLER: That's all right. 5 BY MR. TRISCHLER: 6 Q. So dosing a rat for about 20 weeks or 7 20% of its life expectancy would be the equivalent 8 of dosing a human for about 15 years, correct? 9 A. Yeah. 10 Q. And you understand that when we talk 11 about this case for just a moment, you understand 12 that there's no plaintiff in this litigation who 13 ingested valsartan-containing medications 14 containing nitrosamines for 15 years, right? 15 A. Correct. 16 Q. And the total dose that was given to 17 these rats in your study was listed as 0.33 18 mmol/kilogram. 19 Is that right? 20 A. Yes. 21 Q. Can you equate that to a human dose 22 for a 150-pound individual? 23 A. You want me to do that now? 24 Q. Are you able to? 25 A. I'm able to, yeah, but I don't know</p>
Page 70	Page 72
<p>1 not IV. 2 Q. Okay. 3 So we had a group of 30 rats that 4 were given subcutaneous injection doses of NNK for 5 20 weeks, right? 6 A. Yes. 7 Q. Another group of 30 that were given 8 NNK for the same period of time? 9 A. Correct. 10 Q. By the way, 20 weeks is about 20% of 11 the life expectancy of a rat, right? 12 A. Twenty weeks, something like that. 13 MR. SLATER: Before we continue, can 14 you please put that document in the folder so 15 it would be accessible to everybody? 16 MR. TRISCHLER: Sure. 17 THE VIDEOGRAPHER: It should be in 18 there. Are you not seeing it? I would just 19 suggest -- 20 MR. SLATER: Not there. 21 MR. TRISCHLER: All the exhibits 22 should be placed in the chat or in a folder 23 for everyone's -- 24 THE VIDEOGRAPHER: Just try to 25 refresh the page.</p>	<p>1 if I could do it in my head. So 0.3 millimoles 2 per kilogram, so a 150-pound person is about 3 70 kilograms. 0.3 millimoles per 70 kilograms 4 would be -- I don't know. I can't do it in my 5 head. I'm sorry. 6 Q. That's fair. I couldn't do it 7 either. 8 I'll represent to you I did run 9 this -- 10 A. It's significantly higher than the 11 human dose, if that's what you're getting to. We 12 don't have to waste time going through -- I mean, 13 the purpose of this experiment was to compare NNK 14 and DMN -- NDMA. 15 Q. Understood. 16 A. The dose -- the dose is far higher 17 than a human dose. If you want to get to human 18 dose, you have to look at the Peto study. 19 Q. We'll get there. 20 What we can agree upon is that in 21 this particular study that the dose administered 22 to rats was on order of magnitude greater than the 23 nitrosamine levels seen in valsartan-containing 24 medications, correct? 25 A. Yes, absolutely.</p>

<p style="text-align: right;">Page 73</p> <p>1 Q. And there is a formula for converting 2 these doses to a human equivalent dose, correct? 3 A. Yes. 4 Q. I think we can agree that formula is 5 not easy to do in one's head, but I've done the 6 math and I'll represent to you that the human 7 equivalent dose in this study would equate to 8 about 336 million nanograms. 9 Does that sound about right? 10 A. I'll take your word for it. But I 11 mean this study was not designed to look at human 12 doses at all. 13 Q. It wasn't designed to look -- 14 A. It was designed to compare NNK and 15 NDMA carcinogenicity and metabolism using the 16 doses of NNK that we knew induced a certain 17 percentage of lung tumors. 18 Q. This study that we marked as Exhibit 19 4 was not designed to look at issues of human 20 carcinogenicity of NDMA, correct? 21 A. That's a very broad statement. It 22 wasn't designed to replicate the human dose of 23 NDMA. Not at all. 24 Q. Okay. 25 The point is that the animals in your</p>	<p style="text-align: right;">Page 75</p> <p>1 A. Yes. 2 Q. NDMA is not? 3 A. Correct. It's 2A. 4 THE VIDEOGRAPHER: Counsel, I just 5 want to let you know I have about ten minutes 6 left on this media before I need to do a 7 quick break to change. 8 MR. SLATER: Why is that? Aren't you 9 just recording with the Zoom? 10 THE VIDEOGRAPHER: We run an hour and 11 a half. It's a Veritext standard. 12 MR. SLATER: Well, is it 13 technological issue or is it just a Veritext 14 standard? 15 THE VIDEOGRAPHER: Well, you know, it 16 necessitates the issue that if we go two 17 hours and it crashes, we lose two hours as 18 opposed -- 19 MR. SLATER: Okay. I got it. It's a 20 Veritext issue. Thank you. 21 You can continue. 22 MR. TRISCHLER: Adam, would you want 23 to stop now or go -- 24 MR. SLATER: I've never heard of any 25 such thing. I've been in 100 depositions in</p>
<p style="text-align: right;">Page 74</p> <p>1 study were administered nitrosamines in far 2 greater quantities and over a greater period of 3 their life span than any plaintiff in this 4 litigation. 5 Can we agree on that? 6 A. That's the point you're making, yes. 7 Q. And is the point I'm making accurate? 8 A. Yes. 9 Q. After a long period of exposure at 10 doses far higher than what's contained in any of 11 the valsartan-containing medications, what your 12 study showed was a development of tumors in six of 13 the 30 rats that were administered these high, 14 high doses of NDMA, right? 15 A. Yes. 16 MR. SLATER: Objection. 17 Lack of foundation and multiple other 18 objections. 19 You can answer. 20 A. Yes. 21 Q. In the conclusion of your study was 22 that NNK is more potent than NDMA? 23 A. That was the conclusion. 24 Q. And we know today that NNK and NNN 25 are Class 1 known carcinogens, right?</p>	<p style="text-align: right;">Page 76</p> <p>1 the last year and I haven't heard anyone say 2 we need to stop because of the media cut off. 3 There's a first for everything. We want to 4 use as much time as we can and keep going. 5 MR. TRISCHLER: Bill, you could take 6 down Exhibit 4. 7 BY MR. TRISCHLER: 8 Q. So before we started talking 9 specifically about your paper that we marked as 10 Exhibit 4, Dr. Hecht, I was asking about your 11 bibliography. 12 Those 618 entries that are on it, do 13 any of them deal specifically with the 14 carcinogenicity of NDEA? 15 A. No. 16 Q. Other than the comparative paper that 17 we marked as Exhibit 4, do any of those 618 papers 18 that you list on your bibliography deal with the 19 carcinogenicity of NDMA in any way? 20 A. No. 21 Q. You also list on your -- as part of 22 your CV that we marked as Exhibit 2 some 280 23 chapters, articles and what's called other papers. 24 Are you familiar with that section of 25 your CV, sir?</p>

<p style="text-align: right;">Page 77</p> <p>1 A. Yes.</p> <p>2 Q. Do any of those 280 chapters,</p> <p>3 articles or other papers deal specifically with</p> <p>4 the carcinogenicity of NDMA?</p> <p>5 A. Yes.</p> <p>6 Q. Can you tell me which ones?</p> <p>7 A. No. I've written a number of</p> <p>8 chapters for books dealing with the metabolic</p> <p>9 activation or metabolism usually of nitrosamines</p> <p>10 and NDMA metabolism is kind of the classic</p> <p>11 example. So in a number of those chapters, NDMA</p> <p>12 will have been used as an example of the metabolic</p> <p>13 activation process by which nitrosamines are</p> <p>14 metabolized and bind to DNA leading to miscoding</p> <p>15 and activation of ANCA genes and cancer.</p> <p>16 Q. You've told me --</p> <p>17 A. That's covered in a number of those</p> <p>18 book chapters.</p> <p>19 Q. You told me that you have your report</p> <p>20 in front of you in a hard copy form and I know the</p> <p>21 bibliography is part of the report.</p> <p>22 What I'd ask you to do is go to the</p> <p>23 section marked "Chapters, Invited Articles, Books</p> <p>24 and Other Papers" and look at it and identify for</p> <p>25 me a few of the places that I can go to read what</p>	<p style="text-align: right;">Page 79</p> <p>1 ten minutes and come back.</p> <p>2 THE VIDEOGRAPHER: The time is 10:37.</p> <p>3 We're going off the video record.</p> <p>4 This ends media one.</p> <p>5 (Recess taken)</p> <p>6 THE VIDEOGRAPHER: The time is now</p> <p>7 10:49.</p> <p>8 This begins media two.</p> <p>9 You may proceed.</p> <p>10 Q. Welcome back, Dr. Hecht.</p> <p>11 Before we took a break, we were</p> <p>12 talking about the section of your bibliography</p> <p>13 that's part of Exhibit 2 entitled "Chapters,</p> <p>14 Invited Articles, Books and Other Papers."</p> <p>15 Do you remember that?</p> <p>16 A. Yes.</p> <p>17 Q. Have you been able to find that</p> <p>18 section of your bibliography on your desktop</p> <p>19 there?</p> <p>20 A. Yes.</p> <p>21 Q. I had asked if you would be kind</p> <p>22 enough to peruse that section and just identify</p> <p>23 for me a couple of the publications that you were</p> <p>24 a part of that discuss NDMA.</p> <p>25 A. Right. I couldn't quite do that, so</p>
<p style="text-align: right;">Page 78</p> <p>1 you've written about NDMA.</p> <p>2 A. Okay. Well, I don't have the hard</p> <p>3 copy of the bibliography in front of me, so I'll</p> <p>4 have to pull it up on my computer. Then I can go</p> <p>5 through and then I can tell you. That'll take a</p> <p>6 few minutes.</p> <p>7 MR. TRISCHLER: All right. We need</p> <p>8 to take a break for the videographer, so</p> <p>9 let's take a break. If you don't mind</p> <p>10 looking at that --</p> <p>11 MR. SLATER: No, Clem. We're not</p> <p>12 going to do that during the break. I don't</p> <p>13 want to him doing work that should be on the</p> <p>14 record during a break.</p> <p>15 MR. TRISCHLER: Well, we could do</p> <p>16 it when we come back then, Adam --</p> <p>17 MR. SLATER: Yeah, I just want him to</p> <p>18 be able to take a break, stretch his legs and</p> <p>19 all.</p> <p>20 MR. TRISCHLER: That's fine.</p> <p>21 Whatever you want to do. Let's take a break,</p> <p>22 we'll get the medium up and running and when</p> <p>23 you're ready to come back, we will pick up</p> <p>24 with this.</p> <p>25 MR. SLATER: Let's take no more than</p>	<p style="text-align: right;">Page 80</p> <p>1 I have to -- that'll take some more time.</p> <p>2 Q. You could do it now.</p> <p>3 A. Okay.</p> <p>4 (Witness reviews document)</p> <p>5 Q. Dr. Hecht, may I make a suggestion</p> <p>6 while you're doing this?</p> <p>7 A. Yes.</p> <p>8 Q. If you have located three or four</p> <p>9 that are responsive, that's all I need. I'm not</p> <p>10 looking for you to tell me every single one. Just</p> <p>11 a few.</p> <p>12 A. Okay. So the question is whether</p> <p>13 they specifically have dimethylnitrosamine as</p> <p>14 opposed to nitrosamines in general, correct?</p> <p>15 Q. Correct.</p> <p>16 A. That's the problem I'm having because</p> <p>17 I don't remember whether I specifically talked</p> <p>18 about dimethylnitrosamine, but -- so there's one</p> <p>19 paper in Environmental and Occupational Medicine,</p> <p>20 Third Edition, 1998. It's a chapter on</p> <p>21 N-nitrosamines.</p> <p>22 Q. What number on the bibliography, sir?</p> <p>23 A. It's 149 under the "Chapters"</p> <p>24 section. One forty-nine. That would be an</p> <p>25 example.</p>

<p style="text-align: right;">Page 81</p> <p>1 Q. I'll accept that. You don't need to 2 look at any further. 3 A. All right. 4 Q. So let me ask sort of the same 5 question, but this time related to NDEA. 6 Do any of the chapters, invited 7 articles, books or other papers listed in your CV 8 that we've marked as Exhibit 2 specifically deal 9 with or discuss the carcinogenicity after NDEA? 10 A. No, I don't believe so. 11 Q. Are you familiar with the term 12 "threshold dose" as used in the field of 13 toxicology? 14 A. Yes. 15 Q. What do you understand that term to 16 mean, sir? 17 A. A dose below which there would be no 18 effect. 19 Q. By no effect, you mean no toxicity or 20 harm is -- 21 A. Right. Whatever the end point is. 22 Q. In your career, have you ever done 23 any original research to evaluate or establish a 24 threshold dose for NDMA in humans? 25 A. No.</p>	<p style="text-align: right;">Page 83</p> <p>1 MR. SLATER: Objection. 2 You can answer. 3 A. Yes. 4 Q. Do you intend to offer any opinions 5 asserting that valsartan is not effective in 6 treating hypertension? 7 A. No. 8 Q. Do you intend to offer any opinion 9 that the small amounts of nitrosamine impurities 10 found in certain valsartan-containing medications 11 compromised, limited or reduced the medication's 12 effectiveness in controlling blood pressure? 13 MR. SLATER: Objection to the form. 14 A. No. 15 Q. You personally do not treat heart 16 disease, correct? 17 A. Correct. 18 Q. You're not an expert in the 19 diagnosis, treatment, management of this 20 condition; fair to say? 21 A. Correct. 22 Q. Have you ever been prescribed 23 valsartan-containing medications? 24 MR. SLATER: Objection. 25 Don't answer the question.</p>
<p style="text-align: right;">Page 82</p> <p>1 Q. Have you ever done any research to 2 evaluate a threshold dose for NDEA in humans? 3 A. No. 4 Q. Let me ask a little bit about 5 valsartan if I can. 6 Do you understand that valsartan 7 falls into a class of drugs known as angiotensin 8 receptor blockers or ARBs? 9 A. Yes. 10 Q. Do you understand that ARBs are used 11 in the treatment and management of hypertension? 12 A. Yes. 13 Q. Hypertension and heart disease are 14 the number one cause of death of adults in 15 America; true? 16 A. Yes. 17 Q. Do you agree that 18 valsartan-containing medications have proven to be 19 effective in the treatment and management of this 20 deadly condition? 21 A. Yes. 22 Q. Do you agree that 23 valsartan-containing medications are an important 24 tool for clinicians to manage and treat this 25 deadly disease?</p>	<p style="text-align: right;">Page 84</p> <p>1 I don't think it's appropriate to ask 2 an expert, whatever the question is about, 3 about their own personal health history. 4 MR. TRISCHLER: Only reason I ask, 5 Adam, is if he could be a potential 6 plaintiff, it goes to bias. If he's used 7 these medications, it's certainly relevant. 8 MR. SLATER: That's why you're asking 9 the question? To find out if there's a bias 10 issue? 11 MR. TRISCHLER: To find out if he's 12 used the medications that he's claiming -- 13 MR. SLATER: I'll let Dr. Hecht -- 14 MR. TRISCHLER: If he has a potential 15 claim, I think it's relevant. 16 MR. SLATER: All right. 17 I'll allow Dr. Hecht to answer one 18 question of whether he's used valsartan. 19 A. No, I haven't. 20 Q. Can we agree that hypertension is a 21 major health problem? 22 A. Yes. 23 Q. Are you aware that the CDC is 24 estimating that 45% of adult Americans suffer from 25 hypertension?</p>

<p style="text-align: right;">Page 85</p> <p>1 MR. SLATER: Objection to all these 2 statistical proffers. 3 You can answer. 4 A. I didn't know that number offhand, 5 but, you know, I'll take your word for it. 6 Q. Does hypertension cause cancer? 7 A. No. 8 Q. Is hypertension is risk factor for 9 cancer? 10 A. No. 11 Q. As someone who is -- 12 A. It's not a known risk factor. 13 Q. Are you aware of whether or not there 14 are peer reviewed -- strike that. 15 Are you aware as to whether or not 16 there is peer-reviewed literature that's been 17 published in the medical community noting a 18 statistically significant association between 19 hypertension and cancer? 20 A. I'm not aware of it. I may have seen 21 it. I can't think of it right now. 22 Q. As part of your work in this case, 23 did you do a literature search to determine 24 whether or not there was peer-reviewed literature 25 discussing, noting or observing a statistically</p>	<p style="text-align: right;">Page 87</p> <p>1 Would you agree? 2 A. Yes. 3 Q. While there's certainly no 4 guarantees, what we believe is that a good diet, 5 exercise and good health can go a long way in 6 reducing an individual's risk; true? 7 A. There's plenty of evidence, yes. 8 Q. Based on that, would you agree that 9 hypertension can and does lead to cancer? 10 MR. SLATER: Objection. 11 You can answer. 12 A. So you can construct a connection, I 13 suppose, because, you know, good health, exercise 14 will be good in preventing hypertension and also 15 preventing cancer, so ... 16 In that respect, there could be a 17 connection, sure. 18 Q. Is it fair to say that every 19 plaintiff in this litigation was at an increased 20 risk of developing cancer before they ever took a 21 single valsartan pill? 22 MR. SLATER: Objection. 23 A. I have no idea. 24 Q. Are you aware of any peer-reviewed 25 research published in the medical journals finding</p>
<p style="text-align: right;">Page 86</p> <p>1 significant observation between hypertension and 2 cancer? 3 A. No, I did not. 4 Q. Have you ever done such a literature 5 search? 6 A. Not recently. 7 Q. Can we agree that cancer causation is 8 multifactorial? 9 A. Yes. 10 Q. I think in going through your CV one 11 of the things I observed in connection with your 12 work as a professor or research that you've done, 13 much of it is focused on cancer prevention, 14 correct? 15 A. Correct. 16 Q. As someone who is focused on cancer 17 prevention, one of the things that we've been 18 taught is that good health and good diet can go a 19 long way to reducing an individual's risk factor 20 for developing cancer, correct? 21 A. Yes. 22 Q. While we know, based on the research 23 that's been done in the past few decades, there 24 are things we could do to reduce our risk factor 25 to cancer, we still don't know what causes cancer.</p>	<p style="text-align: right;">Page 88</p> <p>1 a statistically significant increased risk of 2 kidney, colorectal, breast and other cancers in 3 patients with hypertension? 4 MR. SLATER: Objection. 5 There's a massive lack of foundation 6 and relevance, but you can answer the 7 question. Plus -- I said foundation. 8 You can answer. 9 A. Not offhand. 10 Are you still there? 11 Q. Yes, I'm just thinking what I want to 12 ask you next. 13 You told me that research and work 14 that's been done over the years will tell us that 15 cancer can be caused by many different things, one 16 of them being smoking and tobacco use, right? 17 A. Yes. 18 Q. You identified obesity as a risk 19 factor that can lead to cancer, right? 20 A. Yes. 21 Q. Alcohol use can lead to cancer, 22 correct? 23 A. Yes. 24 Q. Radiation can lead to cancer? 25 A. Yes.</p>

<p style="text-align: right;">Page 89</p> <p>1 Q. Genetics can play a role?</p> <p>2 A. Yes.</p> <p>3 Q. Viruses in some circumstances can</p> <p>4 cause cancer?</p> <p>5 A. Yes.</p> <p>6 Q. Environmental -- we believe that some</p> <p>7 environmental exposures can cause cancer, correct?</p> <p>8 A. Yes. Yes.</p> <p>9 Q. Are there other groups of causes that</p> <p>10 are risk factors that we haven't talked about?</p> <p>11 A. I don't know. I think you covered</p> <p>12 the main ones. Sunlight, UV exposure I don't</p> <p>13 think you mentioned.</p> <p>14 Q. Okay.</p> <p>15 Given all these potential causes of</p> <p>16 cancer, are you able to look at a mutation at a</p> <p>17 cellular level and say that that mutation was</p> <p>18 caused by a specific exposure or condition?</p> <p>19 A. That would be very difficult.</p> <p>20 Q. So I'm only asking about you, whether</p> <p>21 you had that ability or capability.</p> <p>22 Do you have the expertise to look at</p> <p>23 a given mutation and say this was caused by</p> <p>24 increased nitrosamine intake as opposed to</p> <p>25 genetics, as opposed to alcohol use, as opposed to</p>	<p style="text-align: right;">Page 91</p> <p>1 for NDMA or NDEA in human tissue and given that</p> <p>2 there are multiple risk factors for cancer, are</p> <p>3 you able to state to a reasonable degree of</p> <p>4 scientific certainty that cancer causation in any</p> <p>5 of these plaintiffs in this litigation was caused</p> <p>6 by nitrosamines?</p> <p>7 MR. SLATER: Objection.</p> <p>8 You can answer.</p> <p>9 A. I wouldn't say there's no biomarker.</p> <p>10 You mentioned certain mutations. But if I find --</p> <p>11 if I'm able to obtain a DNA sample from one of the</p> <p>12 patients, for example, from their oral cells after</p> <p>13 they took a contaminated pill and analyzed the DNA</p> <p>14 in that sample and I find O6-methylguanine in that</p> <p>15 DNA, I can be reasonably sure that came from</p> <p>16 dimethylnitrosamine. So that's a biomarker.</p> <p>17 Q. Have you obtained DNA samples from</p> <p>18 any of the plaintiffs in this case?</p> <p>19 A. No.</p> <p>20 Q. Have you looked for signs of</p> <p>21 O6-methylformane in any of the DNA samples</p> <p>22 or tissue samples from any of the plaintiffs in</p> <p>23 this case?</p> <p>24 A. O6-methylguanine.</p> <p>25 Q. Guanine.</p>
<p style="text-align: right;">Page 90</p> <p>1 any other factor known to cause cancer?</p> <p>2 MR. SLATER: Objection.</p> <p>3 You can answer.</p> <p>4 A. I didn't quite hear your question.</p> <p>5 Did you say patient or mutation?</p> <p>6 Q. Mutation I said.</p> <p>7 A. Well, some mutations are quite</p> <p>8 specific. For example, those caused by UV light,</p> <p>9 you get thymidine cross links in DNA. I'm not</p> <p>10 aware if those are caused by any other agent, so</p> <p>11 there are cases of certain mutations that are</p> <p>12 quite specific.</p> <p>13 Q. Are you aware of any unique</p> <p>14 biomarkers caused by NDMA?</p> <p>15 A. No.</p> <p>16 Q. Are you aware --</p> <p>17 A. Wait. That depends what you mean by</p> <p>18 biomarkers.</p> <p>19 Q. Are you able to look at a mutation</p> <p>20 and say this mutation was caused by NDMA exposure?</p> <p>21 A. No, not a mutation.</p> <p>22 Q. Are you able to look at a mutation</p> <p>23 and say this mutation was caused by NDEA exposure?</p> <p>24 A. No.</p> <p>25 Q. So if there are no unique biomarkers</p>	<p style="text-align: right;">Page 92</p> <p>1 A. Guanine. G-U-A-N-I-N-E.</p> <p>2 No, I haven't. But that would be a</p> <p>3 possible approach, a research approach.</p> <p>4 Q. The presence of O6-methylguanine in a</p> <p>5 DNA sample is not the equivalent of a -- does not</p> <p>6 mean there's a carcinogenic tumor, correct?</p> <p>7 A. Correct. But it's one step in a</p> <p>8 well-established pathway.</p> <p>9 Q. Is the presence of O6-methylguanine</p> <p>10 specific and limited to NDMA and NDEA exposure?</p> <p>11 A. No.</p> <p>12 Q. Going back to my question, you told</p> <p>13 me that you cannot look at a biopsied tissue and</p> <p>14 make the determination that that mutation was</p> <p>15 caused by NDMA, correct?</p> <p>16 MR. SLATER: Objection.</p> <p>17 You can answer.</p> <p>18 A. In the absence of other data, but if</p> <p>19 I had DNA from that tissue and I analyzed it for</p> <p>20 O6-methylguanine and I find O6-methylguanine and</p> <p>21 the mutation is a mutation in a raised gene and I</p> <p>22 have tissue from subjects who did not use</p> <p>23 valsartan and I don't find the mutation, that</p> <p>24 would be pretty good evidence.</p> <p>25 Q. None of that work has been done in</p>

<p style="text-align: right;">Page 93</p> <p>1 this case; is that right?</p> <p>2 A. As far as I know.</p> <p>3 Q. You've not done it?</p> <p>4 A. No.</p> <p>5 Q. What causes the presence of</p> <p>6 O6-methylguanine in a DNA sample?</p> <p>7 A. From the metabolism of a substance</p> <p>8 such as NDMA that leads to the formation of methyl</p> <p>9 diazohydroxide, which reacts with guanine in DNA</p> <p>10 to form O6-methylguanine.</p> <p>11 Q. My question was other than NDMA what</p> <p>12 other substances are you aware of that lead to the</p> <p>13 formation of O6-methylguanine?</p> <p>14 A. Other methylating carcinogens, NNK,</p> <p>15 methyl methane sulfonate. I don't think there's</p> <p>16 much human exposure to that. So, you know, any</p> <p>17 methyl nitroso compound.</p> <p>18 Q. I'm sorry. I didn't mean to</p> <p>19 interrupt you. Go ahead.</p> <p>20 A. I'm done.</p> <p>21 Q. Can the presence of O6-methylguanine</p> <p>22 be attributed in a DNA sample be attributed to</p> <p>23 anything other than exposure to nitrosamines?</p> <p>24 MR. SLATER: Objection.</p> <p>25 You can answer.</p>	<p style="text-align: right;">Page 95</p> <p>1 unique ability not to endogenously create</p> <p>2 nitrosamines?</p> <p>3 MR. SLATER: Objection.</p> <p>4 You can answer.</p> <p>5 A. Not offhand.</p> <p>6 Q. Right. So here's what I don't</p> <p>7 understand: If all of us or virtually all of us</p> <p>8 endogenously create nitrosamines, then every DNA</p> <p>9 sample that you are look at is going to have</p> <p>10 O6-methylguanine.</p> <p>11 A. No, that's not true.</p> <p>12 Q. You just said that nitrosamine</p> <p>13 exposure -- strike that.</p> <p>14 A. Just because you're exposed to a</p> <p>15 nitrosamine doesn't mean that you'll be able to</p> <p>16 necessarily metabolize it efficiently enough to</p> <p>17 alkylate DNA. So you might have cases where the</p> <p>18 exposure is too low or the metabolism is not that</p> <p>19 efficient. It doesn't -- you can't say all.</p> <p>20 Q. O6-methylguanine observed in a DNA</p> <p>21 sample is caused by the metabolism of nitrosamines</p> <p>22 among other things.</p> <p>23 That's what you've told me, right?</p> <p>24 A. Yes.</p> <p>25 Q. When you find O6-methylguanine in a</p>
<p style="text-align: right;">Page 94</p> <p>1 A. Yes, it could be another methylating</p> <p>2 agent. Wouldn't necessarily have to be</p> <p>3 nitrosamine. Methyl methane sulfonate is one of</p> <p>4 the more common ones, but it's not really found in</p> <p>5 the environment.</p> <p>6 Q. I'm going to go into this more a</p> <p>7 little later, but all of us are exposed to</p> <p>8 nitrosamines every single day, correct?</p> <p>9 MR. SLATER: Objection.</p> <p>10 You can answer.</p> <p>11 A. Many people are, yes.</p> <p>12 Q. And all of us process and develop</p> <p>13 nitrosamines endogenously.</p> <p>14 Our body creates them, right?</p> <p>15 A. Yes, to a certain extent.</p> <p>16 Q. Every single day?</p> <p>17 MR. SLATER: Objection.</p> <p>18 A. I don't know about every single day.</p> <p>19 The measurement of endogenous formation is fraught</p> <p>20 with difficulties, but there is certainly the</p> <p>21 evidence for endogenous formation of nitrosamines.</p> <p>22 Q. By all of us?</p> <p>23 A. I don't know about all of us.</p> <p>24 Q. Are you aware of any research that</p> <p>25 suggests there are some individuals that have the</p>	<p style="text-align: right;">Page 96</p> <p>1 DNA sample, if you were to ever do this work, you</p> <p>2 would not be able to tell us whether that</p> <p>3 O6-methylguanine was from nitrosamines ingested</p> <p>4 exogenously or developed endogenously, would you?</p> <p>5 MR. SLATER: Objection.</p> <p>6 You can answer.</p> <p>7 A. I could do a study that could</p> <p>8 indicate that.</p> <p>9 Q. You've not done such a study?</p> <p>10 A. No.</p> <p>11 Q. No one in the world has done such a</p> <p>12 study at this point?</p> <p>13 A. I don't know.</p> <p>14 Q. Are you aware of any?</p> <p>15 A. No. I could compare subjects who</p> <p>16 took contaminated valsartan and who did not and</p> <p>17 get DNA samples from those individuals and analyze</p> <p>18 them for O6-methylguanine and see if there's a</p> <p>19 difference.</p> <p>20 Q. Okay. You could do that --</p> <p>21 A. That would be a good start.</p> <p>22 Q. Great.</p> <p>23 But my question was you haven't done</p> <p>24 that scientific investigation, correct?</p> <p>25 A. No, but I think it would be a good</p>

<p style="text-align: right;">Page 97</p> <p>1 project. You gave me an idea.</p> <p>2 Q. At least I served some purpose here</p> <p>3 today then.</p> <p>4 I want to go back and sort of touch</p> <p>5 on one of the things that I asked you at the</p> <p>6 outset and that relates to the work that you have</p> <p>7 done in this case.</p> <p>8 I think you told me that when you</p> <p>9 wrote your report that you acknowledged that</p> <p>10 valsartan -- whether or not nitrosamines in</p> <p>11 valsartan-containing medications were capable of</p> <p>12 causing cancer is dependent on the exposure, the</p> <p>13 dose and the duration.</p> <p>14 Do you remember telling me that?</p> <p>15 A. Mm-hmm.</p> <p>16 MR. SLATER: Objection.</p> <p>17 You can answer.</p> <p>18 Q. You have to say "yes" or "no" for the</p> <p>19 record.</p> <p>20 A. Yes.</p> <p>21 Q. You gave me a general overview of</p> <p>22 some of the things that you did to try and answer</p> <p>23 the question of whether or not the exposure to</p> <p>24 nitrosamines in valsartan-containing medications</p> <p>25 was capable of increasing the risk of cancer and</p>	<p style="text-align: right;">Page 99</p> <p>1 Q. So if I were to --</p> <p>2 A. But I'm not an encyclopedia, you</p> <p>3 know. I could have forgotten things here and</p> <p>4 there.</p> <p>5 Q. Well, that's what -- I'm not</p> <p>6 suggesting you should be an encyclopedia.</p> <p>7 Would you agree with me that</p> <p>8 formulating a meaningful and reliable opinion on a</p> <p>9 causality of exposure to a disease requires an</p> <p>10 evaluation of the totality of the evidence?</p> <p>11 MR. SLATER: Objection.</p> <p>12 A. Yes.</p> <p>13 Q. So what I'm trying to get a feel for</p> <p>14 and what I'd like you to explain for me is how did</p> <p>15 you set out to make sure that your encyclopedic</p> <p>16 knowledge of the literature was adequate --</p> <p>17 MR. SLATER: Objection.</p> <p>18 You can answer.</p> <p>19 Q. -- before whether it needed to be</p> <p>20 supplemented by a literature review?</p> <p>21 MR. SLATER: Objection.</p> <p>22 You can answer again.</p> <p>23 A. Sure. I needed to review the</p> <p>24 available literature on valsartan, you know, the</p> <p>25 contamination with nitrosamines. I also needed to</p>
<p style="text-align: right;">Page 98</p> <p>1 you said that one of the things you did was</p> <p>2 consult literature.</p> <p>3 Correct?</p> <p>4 A. Yes.</p> <p>5 Q. How did you go about deciding upon</p> <p>6 the literature that you were going to review and</p> <p>7 cite and rely upon in your report?</p> <p>8 A. From my experience and from staying</p> <p>9 up to date on the literature. It's one of the</p> <p>10 things that we do in research, follow the</p> <p>11 literature and attempt to read it all and use it</p> <p>12 our research and let it inform us as to our</p> <p>13 projects and conclusions. So, you know, it's</p> <p>14 important to follow the literature. It's</p> <p>15 something that all researchers do.</p> <p>16 Q. Understood.</p> <p>17 When you were retained by Mr. Slater</p> <p>18 back in September of 2019, did you do any or</p> <p>19 attempt to any sort of comprehensive search of the</p> <p>20 literature or did you just rely on your knowledge</p> <p>21 and efforts to stay abreast of the literature as</p> <p>22 you described it?</p> <p>23 A. Well, I looked into the valsartan</p> <p>24 literature, but mainly I relied on my knowledge of</p> <p>25 the literature.</p>	<p style="text-align: right;">Page 100</p> <p>1 refresh my memory regarding dimethylnitrosamine</p> <p>2 exposures and cancer in the literature.</p> <p>3 Q. So how do you go about refreshing</p> <p>4 your memory in that matter?</p> <p>5 A. I go to PubMed and put in the right</p> <p>6 terms.</p> <p>7 Q. What search terms did you use to run</p> <p>8 that query?</p> <p>9 A. Oh, I don't remember.</p> <p>10 Q. Do you have a list you created?</p> <p>11 A. No, I don't have a list. I know</p> <p>12 dimethylnitrosamine and cancer. You know, it</p> <p>13 would come up with probably a thousand references</p> <p>14 and then you go from there.</p> <p>15 Q. Were those the search terms you</p> <p>16 actually used or --</p> <p>17 A. No. No. I mean, it's a mix. So I</p> <p>18 relied on my knowledge that's been gained over 45</p> <p>19 years of work in this area. I've looked into the</p> <p>20 literature specifically regarding valsartan and I</p> <p>21 updated my -- refreshed my memory regarding papers</p> <p>22 looking at dimethylnitrosamine occurrence in the</p> <p>23 environment, in food, in water, etc. So I tried,</p> <p>24 you know, to cover as much as I could.</p> <p>25 Q. I'll be honest with you, Dr. Hecht.</p>

<p style="text-align: right;">Page 101</p> <p>1 I'm trying to fact check how you did your work. 2 You said -- you told me that you would have 3 updated your knowledge by a literature search. 4 Are you able to show me the actual 5 search terms you would have used? 6 A. No. 7 Q. Are you able to show me the -- have 8 you retained the print out of the results from 9 your initial PubMed searches as far as what hits 10 you received and so forth? 11 A. No. 12 MR. SLATER: Objection. 13 You can answer. 14 Q. Do you know how many publications you 15 pulled in on your initial search? 16 A. No. 17 Q. One of the things that I asked you to 18 bring with you or to the deposition with a notice 19 and one of the things that your counsel was kind 20 enough to provide to me before we began were your 21 invoices that you've generated in connection with 22 your work in this project. 23 Are you aware of that? 24 A. Yes. 25 Q. Did you provide those invoice</p>	<p style="text-align: right;">Page 103</p> <p>1 A. Yes. 2 Q. You would have billed for your work 3 in connection with this case based on this 4 summary, right? 5 A. Yes. 6 Q. What I'm curious about is when I read 7 this document and look at this document marked as 8 Exhibit 5, I don't see any reference to a 9 literature search being done until -- well, 10 actually in -- I stand corrected -- 12/9/19. It 11 says "Further review and literature search on 12 NDMA, one hour." 13 A. Yes. 14 Q. Is that when you would have done your 15 literature search then? 16 A. That's what it says. 17 MR. SLATER: Objection. 18 You can answer. 19 Q. And your search of the literature 20 would have taken you an hour to do? 21 A. On that particular day, yes. 22 Q. Is there any reference to any 23 literature search on any other day in your 24 records? 25 A. I don't know.</p>
<p style="text-align: right;">Page 102</p> <p>1 documents to counsel so that he could provide them 2 to me? 3 A. Yes. Yes. 4 MR. TRISCHLER: Can we mark those as 5 Exhibit 4? 6 THE VIDEOGRAPHER: Exhibit 4 was the 7 comparative -- 8 MR. TRISCHLER: Exhibit 5. Exhibit 9 5 10 THE VIDEOGRAPHER: What was the name 11 of the document again that you wanted -- 12 MR. TRISCHLER: Invoices. 13 THE VIDEOGRAPHER: Okay. Great. 14 Would you like that up on the screen? 15 MR. TRISCHLER: Yes. 16 (Whereupon, Exhibit 5 was marked for 17 identification.) 18 Q. The documents related to your 19 invoices that we marked as Exhibit 5 consist of 20 four pages. What we're looking at here is the 21 first of those four pages that I have. 22 A. Yes. 23 Q. This appears to me, Dr. Hecht, to be 24 a summary of the work that you did from at least 25 September of 2019 through June of 2020, right?</p>	<p style="text-align: right;">Page 104</p> <p>1 MR. SLATER: You can go to the next 2 page, sir. 3 Can you highlight that for the 4 doctor? 5 Q. Is there any reference to your 6 literature search on this page of the billing 7 records? 8 A. Well, the updated report adding new 9 text and references, so, you know, that could have 10 involved some literature. I really don't 11 remember. 12 Q. How about the next page? 13 A. Right. There's no reference to 14 literature search there. 15 Q. How about the last page? 16 A. That's it. 17 Q. So if we look at all the invoice 18 documents that I've been provided with, what it 19 suggests is that there's only one reference to a 20 literature search and that was for an hour on 21 December of 2019. 22 Is that the extent of the literature 23 search that you -- 24 MR. SLATER: Objection. 25 Lack of foundation.</p>

<p style="text-align: right;">Page 105</p> <p>1 You can answer, Doctor.</p> <p>2 A. I do literature work all the time on</p> <p>3 nitrosamine. It's my part of my work.</p> <p>4 Q. All right.</p> <p>5 I'm talking about -- you said you</p> <p>6 keep abreast of the literature. You're looking at</p> <p>7 it all the time.</p> <p>8 A. Yes.</p> <p>9 Q. You're not an encyclopedia and so you</p> <p>10 did a literature search to supplement your</p> <p>11 knowledge.</p> <p>12 Is that supplement the one hour we</p> <p>13 see in December of 2019?</p> <p>14 MR. SLATER: Objection.</p> <p>15 Foundation.</p> <p>16 Argumentative.</p> <p>17 You can answer.</p> <p>18 A. That's what it says.</p> <p>19 Q. You didn't -- according to your</p> <p>20 billing records, you didn't spend any other time</p> <p>21 on the literature search, right?</p> <p>22 MR. SLATER: Objection.</p> <p>23 You can answer.</p> <p>24 A. I didn't bill for it.</p> <p>25 Q. Do you remember doing it?</p>	<p style="text-align: right;">Page 107</p> <p>1 general consideration of nitrosamine</p> <p>2 carcinogenesis. For that, I used literature that</p> <p>3 I refer to frequently, certain reviews and certain</p> <p>4 specific publications.</p> <p>5 For the literature that refers more</p> <p>6 specifically to valsartan, I referred to the -- a</p> <p>7 couple of publications on valsartan as well as the</p> <p>8 EMA report and maybe a couple of others. I don't</p> <p>9 really remember.</p> <p>10 Q. I think it's probably fair to say</p> <p>11 that your report and the references that you cite</p> <p>12 at the conclusion of the report was not intended</p> <p>13 to include citation to every publication on the</p> <p>14 subject of NDMA and NDEA ever written.</p> <p>15 Fair to say?</p> <p>16 A. Yes.</p> <p>17 Q. So what I'm just wondering is was</p> <p>18 there some method in your mind that you started</p> <p>19 with as to what references you were going to rely</p> <p>20 upon and cite and which ones you were going to</p> <p>21 exclude? Did you have any methodology in that</p> <p>22 regard?</p> <p>23 A. Yes. I focused on the studies that</p> <p>24 are relevant to cancer induction by</p> <p>25 dimethylnitrosamine in humans. Basically, I'm</p>
<p style="text-align: right;">Page 106</p> <p>1 A. As I said, I look at the literature</p> <p>2 almost every day in one form or another, so I</p> <p>3 don't necessarily bill for it. It's part of my</p> <p>4 work. It's part of what I do.</p> <p>5 Q. In your report that you provided to</p> <p>6 us, you have footnotes, footnote references at the</p> <p>7 conclusion of the report, a grand total of about</p> <p>8 146, correct?</p> <p>9 A. Yes.</p> <p>10 Q. It looked to me like the last -- you</p> <p>11 have that report in front of you, sir.</p> <p>12 The last footnote, 146, is a true</p> <p>13 footnote, whereas the other 145 are citations to</p> <p>14 literature, company documents or depositions,</p> <p>15 right?</p> <p>16 A. Yes. Right.</p> <p>17 Q. As it relates to the -- I'm trying to</p> <p>18 distinguish for my question the scientific</p> <p>19 literature from the company documents and</p> <p>20 depositions.</p> <p>21 Okay?</p> <p>22 With respect to scientific</p> <p>23 literature, what was your criteria for inclusion</p> <p>24 or exclusion of literature in your report?</p> <p>25 A. Well, the report starts with a</p>	<p style="text-align: right;">Page 108</p> <p>1 looking at the known, very well established</p> <p>2 pathways by which the dimethylnitrosamines</p> <p>3 metabolized can damage DNA, showing that that also</p> <p>4 occurs in humans, that human metabolism with</p> <p>5 dimethylnitrosamines are very well characterized.</p> <p>6 Then looking at aspects of the</p> <p>7 exposure, putting the dose response studies that</p> <p>8 were carried out in rats, then looking at the more</p> <p>9 specific aspects of the valsartan contamination</p> <p>10 and the resulting exposure to dimethylnitrosamine</p> <p>11 and blending these together to make a logic and</p> <p>12 readable product.</p> <p>13 Q. Were there things that you came</p> <p>14 across --</p> <p>15 A. In order to do that, I don't need to</p> <p>16 review every publication that's ever been written</p> <p>17 on nitrosamines.</p> <p>18 Q. Were there studies that you came</p> <p>19 across in your research and work that found the</p> <p>20 carcinogenicity of NDMA or NDEA in humans to be</p> <p>21 inconclusive or unknown that you omitted from your</p> <p>22 report?</p> <p>23 MR. SLATER: Objection.</p> <p>24 You can answer.</p> <p>25 A. There are many studies that conclude</p>

<p style="text-align: right;">Page 109</p> <p>1 with, you know, statements like, you know, we 2 don't necessarily know whether this particular 3 exposure to products or environments containing 4 NDMA or other carcinogens for that matter actually 5 cause cancer. So I mean, they're all -- you know, 6 all studies have limitations and those limitations 7 are usually described. So I mean, I would say 8 that, you know, virtually every study that I 9 quoted would have some kind of limitation. That's 10 part of science. 11 Q. Right. It sounds like you would 12 agree with me then that there are studies that are 13 not included in your report that found NDMA or 14 NDEA carcinogenicity in humans to be unknown or 15 inconclusive that you didn't discuss or didn't 16 cite. 17 A. Sure, that's possible. 18 Q. The studies -- many of the studies 19 that you ultimately cite are animal studies, 20 correct? 21 MR. SLATER: Objection. 22 You can answer. 23 A. Yes. 24 Q. I think beginning on page seven of 25 your report you have a section titled</p>	<p style="text-align: right;">Page 111</p> <p>1 Q. Genomic instability differs from 2 species to species; true? 3 MR. SLATER: Objection. 4 You can answer. 5 A. Yes. 6 Q. DNA repair capacity differs from 7 species to species; true? 8 MR. SLATER: Objection. 9 A. It's a very general statement. 10 Q. Is it true? 11 A. I don't know. Probably. 12 Q. Metabolic factors differ from species 13 to species; true? 14 MR. SLATER: Objection. 15 You can answer. 16 A. Sure. There can be differences. 17 Q. For instance, the level of metabolic 18 enzymes are not identical from one species to 19 another, correct? 20 MR. SLATER: Objection. 21 You can answer. 22 A. In general, that's probably true. 23 Q. In fact, the level of enzymes are not 24 even homogeneous across the human population? 25 A. Yes, that's true.</p>
<p style="text-align: right;">Page 110</p> <p>1 "Carcinogenicity of Nitrosamines and NDMA and 2 Cancer." 3 Is that right? 4 A. Yes. 5 Q. In this section of the report, you 6 seem to cite and rely upon a series of animal 7 studies to demonstrate the carcinogenicity of 8 NDMA? 9 A. Yes. 10 Q. Is it true that the -- I think we 11 talked about this a little bit in connection with 12 your comparative paper that we mentioned earlier, 13 but is it true that toxicity tests are often 14 performed on animals to gain an understanding of 15 cellular and tissue response to toxins? 16 A. Yes. 17 Q. In an animal study, do you agree that 18 there are many factors that affect the outcome of 19 the test or create uncertainty about its 20 extrapolation into a heterogenous human 21 population? 22 MR. SLATER: Objection. 23 You can answer. 24 A. Sure, there are uncertainties. For 25 sure.</p>	<p style="text-align: right;">Page 112</p> <p>1 Q. Metabolic rates also differ between 2 humans and animals, right? 3 A. It can. 4 Q. The binding efficiency of a foreign 5 substance like NDMA to DNA can also differ across 6 species? 7 MR. SLATER: Objection. 8 You can answer. 9 A. It can. 10 Q. For these and other reasons, most 11 competent scientists recognize that attempts to 12 extrapolate data from animal studies to humans is 13 fraught with peril? 14 MR. SLATER: Objection. 15 A. Fraught with peril? 16 Q. Yes, sir. 17 MR. SLATER: Someone wrote a good 18 question there. 19 A. Strong words. Strong words. 20 MR. SLATER: Objection to the 21 question. 22 You can answer. 23 Q. The question is -- 24 A. There are uncertainties. Sure, there 25 are uncertainties. I wouldn't say it's fraught</p>

<p style="text-align: right;">Page 113</p> <p>1 with peril.</p> <p>2 Q. Would you say it's fraught with</p> <p>3 difficulty?</p> <p>4 MR. SLATER: Objection.</p> <p>5 You can answer.</p> <p>6 A. No, I wouldn't say it's fraught with</p> <p>7 difficulty.</p> <p>8 Q. Well, let me show you --</p> <p>9 A. I would say that -- you like the word</p> <p>10 "fraught." There are uncertainties I would say.</p> <p>11 Q. Sure.</p> <p>12 A. Those are well recognized.</p> <p>13 (Whereupon, Exhibit 6 was marked for</p> <p>14 identification.)</p> <p>15 Q. Let me show you what I'll mark as --</p> <p>16 I think we're up to Exhibit 6. It's a paper by</p> <p>17 Gombar -- G-O-M-B-A-R -- is the lead author. The</p> <p>18 paper is entitled "Pharmacokinetics of</p> <p>19 Nitrosodimethylamine in Beagles."</p> <p>20 Are you familiar with that paper?</p> <p>21 A. Yes.</p> <p>22 Q. I think you cited it in your report,</p> <p>23 correct?</p> <p>24 A. Correct.</p> <p>25 Q. You relied upon it, correct?</p>	<p style="text-align: right;">Page 115</p> <p>1 Q. So now, Dr. Hecht, we're looking at</p> <p>2 the first page of Gombar's study that you cite in</p> <p>3 your report. There's a section on the left-hand</p> <p>4 side of the first page marked "Introduction," if</p> <p>5 you could highlight that section for the doctor.</p> <p>6 Certainly, Doctor, when I show you a</p> <p>7 document like this, you're free to read as much of</p> <p>8 the study as you want, but I wanted to direct your</p> <p>9 attention to the introduction in the second</p> <p>10 paragraph where Gombar and his colleagues note</p> <p>11 that extrapolation of carcinogenicity data from</p> <p>12 animals to humans is fraught with difficulty.</p> <p>13 Do you see that?</p> <p>14 A. Yes, those are the words he used.</p> <p>15 Q. Right.</p> <p>16 Do you agree with Gombar's</p> <p>17 statements?</p> <p>18 A. Not necessarily. I think "fraught</p> <p>19 with difficulty" is a little too strong. You</p> <p>20 know, that's his opinion, so it's okay.</p> <p>21 Q. But you're the one that cited to this</p> <p>22 report, not me, correct?</p> <p>23 MR. SLATER: Objection.</p> <p>24 Argumentative.</p> <p>25 A. I cited it, yeah, that's true. It</p>
<p style="text-align: right;">Page 114</p> <p>1 A. Relied upon it? Sure, I cited it.</p> <p>2 Yes.</p> <p>3 MR. TRISCHLER: Can you put up the</p> <p>4 Exhibit 6 please, the first page of it?</p> <p>5 THE VIDEOGRAPHER: Looking for it</p> <p>6 now. One moment.</p> <p>7 You said in beagles?</p> <p>8 MR. TRISCHLER: Yes.</p> <p>9 THE VIDEOGRAPHER: I'm actually not</p> <p>10 seeing this in the list I was given, one</p> <p>11 related to beagles.</p> <p>12 THE WITNESS: Go to PubMed and enter</p> <p>13 Gombar --</p> <p>14 MR. TRISCHLER: I'll send it now.</p> <p>15 THE VIDEOGRAPHER: Thank you.</p> <p>16 MR. TRISCHLER: You should have it.</p> <p>17 THE VIDEOGRAPHER: One moment while</p> <p>18 it's downloading. That was not one that was</p> <p>19 uploaded before. Maybe it failed in the</p> <p>20 upload.</p> <p>21 MR. TRISCHLER: Must have been the</p> <p>22 one that broke the computer.</p> <p>23 THE VIDEOGRAPHER: Maybe.</p> <p>24 MR. TRISCHLER: Okay.</p> <p>25 BY MR. TRISCHLER:</p>	<p style="text-align: right;">Page 116</p> <p>1 deals with the topic.</p> <p>2 Q. And you agree with me that the</p> <p>3 attempt to -- that there are problems and</p> <p>4 limitations associated with the extrapolation of</p> <p>5 carcinogenicity data from animals to humans; true?</p> <p>6 MR. SLATER: Objection.</p> <p>7 A. There are limitations. Sure, there</p> <p>8 are limitations.</p> <p>9 Q. Gombar and his colleagues go on to</p> <p>10 tell us what some of those limitations are,</p> <p>11 correct?</p> <p>12 A. Yes.</p> <p>13 Q. Some of those limitations include the</p> <p>14 inherited susceptibility of tissues to the</p> <p>15 carcinogenic action of NDMA, the efficiency and</p> <p>16 fidelity of repair processes, quantitative and</p> <p>17 qualitative metabolic aspects and the</p> <p>18 pharmacokinetics of the compound may be very</p> <p>19 different in humans, right?</p> <p>20 A. Yes. It's all true. That's why we</p> <p>21 do research.</p> <p>22 Q. Sure.</p> <p>23 Do you consider yourself a scientist,</p> <p>24 Dr. Hecht?</p> <p>25 A. Yes.</p>

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<p>1 Q. As a scientist, do you agree that 2 it's improper to draw conclusions and inferences 3 from a study that the authors themselves did not 4 support? 5 MR. SLATER: Objection. 6 A. I'm not -- could you repeat that? 7 Q. Sure. 8 Do you agree that it would be 9 improper to draw conclusions or inferences from a 10 study that the authors themselves did not support? 11 MR. SLATER: Hold on, Dr. Hecht. 12 Objection and counsel might want to 13 read Law 360 and the Eighth Circuit's 14 decision from yesterday. 15 You can answer, Dr. Hecht. 16 A. So we draw conclusions from our data. 17 All the data has limitations and we think about 18 and analyze the limitations of the data and that 19 influences our conclusions. 20 Q. Do you ever draw conclusions from a 21 study that the authors of that study themselves 22 reject? 23 MR. SLATER: Objection. 24 You can answer. 25 A. Not in general. Not in general, no.</p>	<p>1 Is that right? 2 A. Yes. 3 Q. Do you know how many nanograms are in 4 a milligram? 5 A. Sure. There's a thousand nanograms 6 in a microgram and there's 1,000 micrograms in a 7 milligram, so there are a million nanograms in 8 a milligram. 9 Q. So the dose that was administered to 10 the rats in the Magee and Barnes study was -- 11 A. Yes, that's correct. 12 Q. Do you know the equivalent dose of 13 25 million nanograms per kilogram in a human being 14 that weighs 150 pounds? 15 A. Not offhand, no. I would have to do 16 the calculation. I can't do it sitting here, 17 talking to you. 18 Q. Would you agree that that dose is on 19 order of magnitude far greater than any dose that 20 would have been given to any plaintiff who took 21 valsartan-containing medications containing some 22 nitrosamines? 23 A. Absolutely. 24 Q. Do you agree that there's no 25 correlation between the dose administered in the</p>
Page 118	Page 120
<p>1 Q. In general, you'd agree that would -- 2 A. Well, no, actually -- so, you know, 3 that depends on the data that's being presented. 4 I mean, I might find errors in their data and then 5 I wouldn't come to the same conclusions. 6 Q. In general, would you -- 7 A. I might find flaws in their 8 experimental approach and then I would reject 9 their conclusions. Just because it's published 10 doesn't mean that it's necessarily correct. 11 Q. One of the papers that you also cited 12 was a paper by Magee and Barnes entitled -- you 13 can take that one down -- entitled "The Production 14 of Malignant Primary Hepatic Tumors in the Rat by 15 Feeding Dimethylnitrosamine." 16 Do you recall that paper? 17 A. Yes, very well. 18 MR. TRISCHLER: I'll mark that as our 19 next numbered exhibit. I think we're up to 20 7. 21 (Whereupon, Exhibit 7 was marked for 22 identification.) 23 Q. In this paper, I believe that the 24 rats were administered NDMA on the order of 25 25 milligrams per kilogram of body weight.</p>	<p>1 Barnes study and what any plaintiff in this case 2 may have received? 3 MR. SLATER: Objection. 4 You can answer. 5 A. I don't know what you mean by "no 6 correlation." This was, as you know, as you're 7 well aware, the first study showing that 8 dimethylnitrosamine causes liver tumors in rats. 9 So naturally, they started with a high dose. 10 That's -- if you don't start with a high dose, 11 then you get a negative result and you still 12 haven't answered the question. 13 If you start with a high dose and you 14 get a negative result, you can be pretty sure that 15 the compound is not a strong carcinogen. Years 16 later, as you know, after literally many, many 17 studies have extended and confirmed this initial 18 study showing that dimethylnitrosamine causes 19 liver cancer in rats, there was the study -- the 20 dose response study by Peto, Grasso and others -- 21 showing going down to extremely low doses. 22 So I don't really see what you're 23 driving at here, sir. 24 MR. TRISCHLER: Object and move to 25 strike as non-responsive.</p>

<p style="text-align: right;">Page 121</p> <p>1 Q. All I was asking you about was the 2 Magee and Barnes study, Doctor. 3 My question was the doses that Magee 4 and Barnes administered to the rats in this study 5 were far and away greater than the levels of 6 nitrosamines that were observed in any 7 valsartan-containing medications. 8 Would you agree? 9 A. Absolutely. 10 Q. And in this same study that we marked 11 as Exhibit 7, did -- I think the authors also 12 tried to duplicate their work on other mammals, 13 namely rabbits, right? 14 MR. SLATER: Objection. 15 You can answer. 16 A. Yes. 17 Q. And there was NDMA that was 18 administered to rabbits in this Magee and Barnes 19 study, correct? 20 A. Yes. 21 Q. How much NDMA was delivered to these 22 rabbits? 23 A. I don't remember. 24 Q. Was it -- 25 A. It was a high dose. I think they</p>	<p style="text-align: right;">Page 123</p> <p>1 Q. While the gentleman is taking care of 2 that for us, Doctor, you not only mentioned the 3 Peto paper a little earlier, you cited to it in 4 your report, correct? 5 A. Yes. 6 Q. In Peto, we have another animal study 7 where NDMA and NDEA were administered to rats, 8 correct? 9 A. Yes. 10 Q. In his work, Peto was careful to note 11 that no extrapolation of this data to humans 12 should be done. 13 Do you agree? 14 A. Yes. 15 Q. In fact, if you can go to page 6445 16 of that paper, the second paragraph of the 17 chart -- there we go -- what Peto wrote is that 18 "It would be a serious distortion of these 19 experimental results to extrapolate this data to 20 humans." 21 Correct? 22 A. That's what he wrote. 23 Q. And so what we know from the Peto 24 study is it provided us with some valuable 25 information on dose response relationship to NDMA</p>
<p style="text-align: right;">Page 122</p> <p>1 also had some toxicity. 2 Q. Was it the same 25 milligrams per 3 kilogram of body weight dose that the -- 4 A. I don't know. Look in the paper. I 5 don't remember. 6 Q. Do you remember that in connection 7 with the rabbits no tumors were observed in this 8 study? 9 MR. SLATER: Objection. 10 You can answer. 11 A. I forgot about the rabbits. 12 MR. TRISCHLER: If you could 13 highlight the second paragraph for me, 14 please. 15 Q. Take a look at it, Doctor. 16 Were any tumors observed in the 17 rabbits in this study? 18 A. No. 19 MR. TRISCHLER: You mentioned the 20 Peto paper, so let me ask you about that. 21 There's a paper by a gentleman named 22 Peto that you just mentioned, P-E-T-O. We 23 can mark that as Exhibit 8. 24 (Whereupon, Exhibit 8 was marked for 25 identification.)</p>	<p style="text-align: right;">Page 124</p> <p>1 that was administered to rats, but it did not 2 provide any reliable information on the effects of 3 nitrosamines on humans, correct? 4 MR. SLATER: Objection. 5 You can answer. 6 A. Correct. 7 Q. I didn't hear your answer, sir. 8 A. Yes, correct. 9 Actually, I wouldn't say any reliable 10 information. I hate to get into a semantic 11 argument. I wouldn't say it doesn't provide any 12 reliable information. It does provide reliable 13 information, well, definitely with respect to 14 rats. You know, whether this information is 15 directly applicable to humans, we don't know, but 16 it does give a strong indication of the strength 17 of the carcinogen and a widely accepted animal 18 model. 19 Q. What Peto said and what he wrote in 20 the peer-reviewed literature was that this data 21 does not provide reliable information as to the 22 effects of a part per billion nitrosamine 23 concentration on humans. 24 Isn't that -- 25 A. That's what he says.</p>

<p style="text-align: right;">Page 125</p> <p>1 Q. And he says it would be a distortion 2 of these experimental results to suggest something 3 different? 4 A. Yes, that's what he said. 5 Q. My question was not asking you about 6 whether Peto's study provides us dose effect -- 7 provides us with relevant and reliable dose effect 8 data on NDMA in rats. 9 I'm talking about humans. When we 10 talk about humans, Peto's study does not provide 11 us with any reliable information. He even said 12 so, right? 13 MR. SLATER: Objection. 14 A. That's what he says. It says it 15 right there. 16 MR. TRISCHLER: I'm going to ask you 17 about another animal study that you cited in 18 your report. I think we'll mark this 19 one Exhibit 9 and it's another paper by 20 Gombar, G-O-M-B-A-R, entitled 21 "Pharmacokinetics of N-nitrosodimethylamine 22 in Swine." 23 (Whereupon, Exhibit 9 was marked for 24 identification.) 25 Q. Do you see that?</p>	<p style="text-align: right;">Page 127</p> <p>1 differing pharmacokinetics from species to 2 species, correct? 3 A. Right. 4 Q. Can we agree that the authors of the 5 animal studies that you cite in your report have 6 repeatedly and consistently cautioned against 7 using this animal data to extrapolate to 8 carcinogenicity in humans? 9 A. They do, yeah. 10 Q. And there's one other statement in 11 this Exhibit 9 that I wanted to ask you about. 12 It's -- I think it's on the first page of the 13 paper under the introduction section if you -- and 14 in this study that you cite in your own report, 15 what Gombar said and what he observes is that it's 16 not yet proven that nitrosamines cause any human 17 cancer. 18 Do you see that? 19 A. Yes. 20 Q. Do you agree with that statement? 21 MR. SLATER: Objection. 22 A. Yes. 23 Sorry, I just had a cramp. 24 Q. Are you okay? 25 A. Yes, I'm okay.</p>
<p style="text-align: right;">Page 126</p> <p>1 A. Yes. 2 Q. In this paper, is it also true, if 3 you recall, that the authors once again cautioned 4 against extrapolating carcinogenicity data from 5 animals to humans? 6 MR. SLATER: Objection. 7 You can answer. 8 A. I don't recall, but I presume that 9 they did. 10 Q. If you go to page 1353, under the 11 "Discussion" section of the paper, first paragraph 12 there, Gombar says once again that extrapolation 13 of carcinogenicity data from laboratory animals to 14 humans is a difficult task because chemical 15 carcinogenesis is a multistep process involving 16 many factors, right? 17 A. True. 18 Q. Do you agree with all that? 19 A. Pardon? 20 Q. Do you agree with all that, sir? 21 A. Yes, I do. 22 Q. While there are many factors that 23 make extrapolation of data from animal studies to 24 humans difficult, one of the things that Gombar 25 and his colleagues note here particularly is the</p>	<p style="text-align: right;">Page 128</p> <p>1 Yes. I mean, that was written about 2 20 years ago, I think. 3 Q. It was written in 1988, I think. 4 A. Okay. So, you know, 33 years ago. 5 Q. Was it correct when written in 1988 6 that -- 7 A. Yeah. 8 MR. SLATER: Let him finish the 9 question so I can place an objection. 10 MR. TRISCHLER: Sorry. We have to go 11 back to pausing there, Doctor. Sometimes -- 12 and I know it can be difficult with the, you 13 know, trying to do this remotely, but let me 14 finish my question. 15 Q. My question was was it true, was 16 Gombar's statement when he wrote it in 1988 that 17 it's not yet been proven that nitrosamines cause 18 any human cancer, was that a true and correct 19 statement when written in 1988? 20 MR. SLATER: Objection. 21 A. Yes. 22 Q. And in the second -- this is the 23 second paper that we looked at from Gombar that 24 you cited in your report and much like the first 25 one, can we agree that the doses that were</p>

<p style="text-align: right;">Page 129</p> <p>1 administered to these animals were far greater 2 than any human equivalent dose? 3 A. They were greater, yes. 4 Q. Far greater? 5 A. But not as greater as the Magee and 6 Barnes paper. The Magee and Barnes paper, they 7 were looking at possible carcinogenicity of a 8 compound. They didn't know whether it was 9 carcinogenic or not, so they started with a high 10 dose. 11 In these papers by Gombar, I don't 12 really remember the dose, but I'm pretty sure it 13 was less than what Magee and Barnes used because 14 this was a pharmacokinetic study. They would have 15 used multiple doses, probably ones that were less 16 than used by Magee and Barnes. 17 Q. Well, if you look at the summary of 18 the paper there in the top left-hand column, the 19 doses are covered. 20 The doses were -- there were doses of 21 NDMA administered both intravenously and orally, 22 correct? 23 A. Yes. 24 Q. And the doses were on the magnitude 25 intravenously that totaled 1.6 milligrams per</p>	<p style="text-align: right;">Page 131</p> <p>1 right? 2 MR. SLATER: Objection. 3 A. Correct. Yes, that's correct. 4 MR. TRISCHLER: You can take that 5 document down, I believe, sir. 6 Thank you. 7 Q. So what we just learned from the 8 Gombar paper was that -- and what we agreed on was 9 that in 1988 there was no evidence demonstrating 10 that nitrosamines caused any human cancer, right? 11 A. I wouldn't say no evidence. I 12 wouldn't say that. 13 Q. All right. Let me rephrase the 14 question. 15 A. We had evidence from -- at that time, 16 we had evidence from tobacco-specific nitrosamines 17 of cancer in humans. 18 Q. Let me ask my question specific to 19 NDMA then. 20 In 1988, we can agree that it had not 21 been proven that NDMA caused any human cancer, 22 right? 23 MR. SLATER: Objection. 24 You can answer. 25 A. Yes, correct.</p>
<p style="text-align: right;">Page 130</p> <p>1 kilogram, right? 2 A. 0.1, 0.5 and 1.0. Those were 3 separate. I don't know why you're adding them 4 together. 5 Q. I was adding them together as a total 6 IV dose. 7 A. Well, that's wrong. I mean, I think 8 they had different animals, different specific 9 animals that were each treated with these three 10 different doses. In other words, the lowest dose 11 would have been 0.1 milligrams per kilogram, not 12 1.6. 13 Q. All right. 14 Then the oral doses were 1.0 15 milligram per kilogram and 5 milligrams per 16 kilogram? 17 A. Yes. 18 Q. There are a million nanograms in a -- 19 A. Yes, they're higher than the human 20 dose. We don't have to go through it again. 21 Q. Please let me finish my question. 22 A. Okay. 23 Q. There are orders of the doses are 24 orders of magnitude higher than what any human 25 would see from valsartan-containing medications,</p>	<p style="text-align: right;">Page 132</p> <p>1 Q. To this day, do you agree that 2 there's no scientific evidence conclusively 3 establishing NDMA as a cause of human cancer? 4 MR. SLATER: Objection. 5 You can answer. 6 A. Well, let me answer it this way. 7 I'll read from the IARC report in 1978. 8 "Although no epidemiologic data was 9 available N-nitrosodimethylamine should be 10 regarded for practical purposes as if it were 11 carcinogenic to humans," IARC, 1978, World Health 12 Organization. 13 Q. Do you agree that there's no 14 scientific evidence conclusively establishing NDEA 15 as a known cause of human cancer? 16 MR. SLATER: Objection. 17 You can answer. 18 A. Yes. 19 Q. Can you cite me to any peer-reviewed 20 publication available in the scientific literature 21 identifying NDMA as a known cause of human 22 cancers? 23 MR. SLATER: Objection. 24 You can answer. 25 A. No.</p>

<p style="text-align: right;">Page 133</p> <p>1 Q. Can you cite me to any peer-reviewed 2 publication available in the scientific literature 3 identifying NDEA as a known cause of human 4 cancers? 5 A. No. 6 Q. Are you aware of any epidemiological 7 study that's found NDMA to be a known cause of 8 cancer in humans? 9 A. Not by itself, but there are a number 10 of epidemiology studies that looked at dietary 11 exposure to NDMA and cancer. 12 Q. Have those -- are you aware of any of 13 those studies that have concluded that NDMA is a 14 known cause of cancer in humans? 15 MR. SLATER: Objection. 16 You can answer. 17 A. Not specifically as you stated it, 18 no. 19 Q. Right. 20 There are studies that suggest there 21 might be an association between NDMA intake and 22 some cancers. 23 My question was are you aware of any 24 epidemiological study that has found NDMA to be a 25 known cause of cancer in humans?</p>	<p style="text-align: right;">Page 135</p> <p>1 Q. IARC is the International Agency for 2 Research on Cancer, correct? 3 A. Yes. 4 Q. You mentioned the World Health 5 Organization. I think IARC is an arm of the World 6 Health Organization, right? 7 A. Yes. 8 Q. IARC has working groups that review 9 available scientific data, prepare monographs and 10 those monographs are then used to classify 11 compounds as carcinogenic or noncarcinogenic, 12 correct? 13 A. Right. 14 Q. IARC has published a monograph 15 for NDMA you pointed out for us on the video a 16 little bit ago, right? 17 A. That was an early one. It also did 18 an update some years later. 19 Q. Okay. Sorry. I didn't realize you 20 were not finished. 21 Were you part of the working group 22 for the NDMA monograph? 23 A. No. 24 Q. In the monograph, the IARC working 25 group noted that there was no case reports or</p>
<p style="text-align: right;">Page 134</p> <p>1 MR. SLATER: Objection. 2 You can answer. 3 A. No. 4 Q. Are you aware of any epidemiological 5 study that has found NDEA to be a known cause of 6 cancer in humans? 7 A. No. 8 Q. Have you ever seen an article or a 9 case study published anywhere in the literature 10 that concludes that a patient's cancer was caused 11 by NDMA? 12 MR. SLATER: Objection. 13 You can answer. 14 A. No. 15 Q. Have you seen any article or case 16 study published anywhere in the literature that 17 has concluded that a patient's cancer was caused 18 by NDEA? 19 MR. SLATER: Objection. 20 You can answer. 21 A. No. 22 Q. You mentioned the IARC report a 23 little bit earlier. 24 Do you remember that? 25 A. Yes.</p>	<p style="text-align: right;">Page 136</p> <p>1 epidemiological studies to assess carcinogenicity 2 in humans; true? 3 A. Yes. 4 Q. IARC has also published a monograph 5 for NDEA, right? 6 A. Yes. Yes. 7 Q. Were you part of the working group 8 for the NDEA monograph? 9 A. No. 10 Q. In the NDEA monograph, the working 11 group of scientists who studied this agent 12 observed that there was no case reports available 13 to assess carcinogenicity in humans, correct? 14 A. Correct. 15 Q. The working group also went on to 16 note there were no available epidemiological 17 studies to assess carcinogenicity of NDEA in 18 humans; true? 19 A. Yes. 20 Q. So based on these monographs, IARC 21 classified both NDMA and NDEA as Class 2A probable 22 carcinogens. 23 A. Probable human carcinogens. Probable 24 human carcinogens. 25 Q. Class 2A?</p>

<p style="text-align: right;">Page 137</p> <p>1 A. Yes. Probable human carcinogens, not 2 probable carcinogens. 3 Q. But they were assigned to Class 2A -- 4 A. Probably carcinogenic to humans. 5 That's what they said. 6 Q. Did you hear my last question? 7 A. 2A. Yeah, 2A. 8 Q. When did IARC develop this 9 classification system? 10 A. I believe it was around 1970. 11 Q. There's a big, long list of compounds 12 that were -- that IARC has classified since 1970, 13 correct? 14 A. Yes. 15 MR. TRISCHLER: I don't know if we 16 have that list or not. 17 On the next break, I'll have that 18 list marked as an exhibit because I don't 19 know if I sent it to the video folks -- 20 THE VIDEOGRAPHER: Counsel, on that 21 note, I have about five minutes left on this 22 media, just to let you know. 23 Q. In any event, when was the Class 2A 24 designation assigned -- first assigned to NDMA? 25 A. That would be 1978.</p>	<p style="text-align: right;">Page 139</p> <p>1 included in Class 1 include tobacco, correct? 2 A. Yes. 3 Q. Is alcohol a Class 1 carcinogen? 4 A. Yes. 5 Q. Asbestos, is that a Class 1 6 carcinogen? 7 A. Yes. 8 Q. Coal? 9 A. Coal tar. 10 Q. Is listed as a Class 1 carcinogen? 11 A. Coal tar. Not coal itself. 12 Q. Okay. 13 The fact is IARC has identified over 14 100 known carcinogens, right? 15 A. You mean Class 1? 16 Q. Yes, sir. 17 A. I believe that's right. 18 Q. To this day, neither NDMA nor NDEA 19 have ever been listed by IARC as known human 20 carcinogen, right? 21 A. Not Class 1, no. 22 MR. TRISCHLER: We need to take a 23 break to change tapes or do whatever the 24 video person needs to do. 25 Adam, what did you want to do about a</p>
<p style="text-align: right;">Page 138</p> <p>1 Q. You said it was updated after 1978? 2 A. Yes. 3 Q. I think that was in 1987? 4 A. Sounds about right. 5 Q. Was the classification changed in -- 6 A. No. Still 2A. 7 Q. When was NDEA first classified as 2A? 8 A. Same. 9 Q. 1970? 10 A. 1978. 11 Q. Seventy-eight. Okay. 12 Was it updated in 1987? 13 A. I believe so. 14 Q. When it was updated in 1987 was the 15 classification of NDEA as a 2A class carcinogen, 16 was it changed? 17 A. No. They're both 2A. 18 Q. To this day, has the classification 19 of NDEA or NDMA ever changed? 20 A. No. Both 2A. 21 Q. From your perspective, the Class 1 22 designation is reserved for known human 23 carcinogens, correct? 24 A. Yes. 25 Q. The known carcinogens that are</p>	<p style="text-align: right;">Page 140</p> <p>1 lunch schedule? 2 MR. SLATER: I want to do whatever 3 Dr. Hecht wants to do. 4 MR. TRISCHLER: Okay. 5 Do you want to -- I'm just asking did 6 you want to -- 7 MR. SLATER: We'll talk during the 8 break how much longer he wants to go before 9 we eat. 10 Is that all right? 11 MR. TRISCHLER: It's okay with me. 12 THE WITNESS: I'm good until about 13 one o'clock your time. 14 MR. TRISCHLER: Okay. 15 Why don't we take a five-minute break 16 to do whatever the technical people need to 17 do and we can go until one o'clock my time, 18 if that's okay with the witness and if it's 19 okay with Adam. 20 MR. SLATER: It's fine. 21 THE WITNESS: How long are we going 22 to break for lunch? 23 MR. TRISCHLER: As long as you want. 24 THE WITNESS: Okay. 25 MR. TRISCHLER: Or as short as you</p>

<p style="text-align: right;">Page 141</p> <p>1 want.</p> <p>2 THE WITNESS: Okay. I need to go out</p> <p>3 and get something.</p> <p>4 MR. TRISCHLER: Okay. Sure, we</p> <p>5 can -- you're in charge of that aspect, so --</p> <p>6 THE WITNESS: Okay.</p> <p>7 THE VIDEOGRAPHER: The time is 12:17.</p> <p>8 This ends media two.</p> <p>9 (Recess taken)</p> <p>10 THE VIDEOGRAPHER: The time is now</p> <p>11 12:27.</p> <p>12 This begins media three.</p> <p>13 You may proceed.</p> <p>14 Q. Doctor, before our last break, we</p> <p>15 were talking a little bit about the IARC</p> <p>16 classification of agents.</p> <p>17 Do you recall that?</p> <p>18 A. Yes.</p> <p>19 Q. I asked you if there was a published</p> <p>20 list where IARC identifies all of the agents that</p> <p>21 have been studied by their grouping or</p> <p>22 classification.</p> <p>23 Do you recall that?</p> <p>24 A. Yes.</p> <p>25 MR. TRISCHLER: So I've gone ahead</p>	<p style="text-align: right;">Page 143</p> <p>1 carcinogenicity in experimental animals?</p> <p>2 A. I think that's how they describe it.</p> <p>3 Q. Do you agree with IARC's</p> <p>4 classification of NDMA and NDEA as Class 2A?</p> <p>5 A. Yes, I agree. But I also agree with</p> <p>6 the statement that they should be regarded for</p> <p>7 practical purposes as if it were carcinogenic in</p> <p>8 humans. That was for NDMA.</p> <p>9 Q. Do you agree --</p> <p>10 A. But yes, I agree that 2A is proper</p> <p>11 because 2A is probably carcinogenic to humans.</p> <p>12 Group one is carcinogenic to humans, so you would</p> <p>13 need an instance where there's been exposure to</p> <p>14 NDMA or NDEA in the absence of other possibly</p> <p>15 causes and, you know, this could be the example,</p> <p>16 valsartan.</p> <p>17 Q. Do you agree that there is limited</p> <p>18 evidence of carcinogenicity in humans for NDMA and</p> <p>19 NDEA?</p> <p>20 MR. SLATER: Objection.</p> <p>21 You can answer.</p> <p>22 A. You know, I'm not sure about limited.</p> <p>23 So, I mean, I know that they do go through each</p> <p>24 sub category in their final evaluation. I don't</p> <p>25 really think it's -- I don't think it's limited at</p>
<p style="text-align: right;">Page 142</p> <p>1 and sent to our technical folks that list and</p> <p>2 I'll have that marked as the next numbered</p> <p>3 exhibit. I think it might be 10.</p> <p>4 THE VIDEOGRAPHER: Ten is correct,</p> <p>5 sir.</p> <p>6 (Whereupon, Exhibit10 was marked for</p> <p>7 identification.)</p> <p>8 Q. I think what you're now looking at is</p> <p>9 the first page of that exhibit. It's 37 pages</p> <p>10 long -- and I think if you could just blow up,</p> <p>11 Bill, some part of it for the witness's benefit --</p> <p>12 this is the list that I was showing you or</p> <p>13 mentioning before, Doctor, and it tells us that</p> <p>14 IARC has prepared monographs for each of these</p> <p>15 agents and classified them by their carcinogenic</p> <p>16 properties, correct?</p> <p>17 A. Yes.</p> <p>18 Q. As we mentioned, included in this</p> <p>19 37-page compendium is NDMA and NDEA, both of which</p> <p>20 are Class 2A, right?</p> <p>21 A. Yes.</p> <p>22 Q. Is it true that the classification of</p> <p>23 an agent as Class 2A is a classification that's</p> <p>24 reserved for agents where there's limited evidence</p> <p>25 of carcinogenicity in humans and sufficient</p>	<p style="text-align: right;">Page 144</p> <p>1 all. I don't agree. No, I don't agree.</p> <p>2 Q. What --</p> <p>3 A. I don't agree that it's limited.</p> <p>4 Q. Okay.</p> <p>5 Is there a process within IARC to</p> <p>6 petition a working group to change a</p> <p>7 classification?</p> <p>8 A. I have no idea.</p> <p>9 Q. At any point in your career have you</p> <p>10 ever submitted any petition, evidence or writings</p> <p>11 to IARC advocating a change in a classification</p> <p>12 for an agent?</p> <p>13 A. No.</p> <p>14 Q. To this point in time, have you</p> <p>15 submitted any petition, evidence or writings to</p> <p>16 IARC advocating a change in the classification for</p> <p>17 NDMA or NDEA?</p> <p>18 A. No, I haven't.</p> <p>19 Q. Outside the context of this</p> <p>20 litigation, have you ever submitted anything to</p> <p>21 any world health authority advocating or</p> <p>22 suggesting that the scientific evidence justified</p> <p>23 reclassifying NDMA and NDEA to known human</p> <p>24 carcinogenic status?</p> <p>25 A. No, I haven't.</p>

<p style="text-align: right;">Page 145</p> <p>1 Q. When we talk about Class 1 known 2 human carcinogens, we mention that among the 3 37-page compendium there are hundreds that have 4 been named as Class 1, right? 5 A. How many? I don't know. 6 Q. Over 100, I said. 7 A. If that's what you say. 8 Q. Okay. 9 A. You've got the list there. 10 Q. Would you agree that many of the 11 Class 1 carcinogens are things that all of us are 12 consuming and are exposed to on a daily basis? 13 A. All of them or many of them? What's 14 your question? 15 Q. Would you agree that many of the 16 Class 1 carcinogens are things that all of us 17 consume or are exposed to on a daily basis? 18 A. No. 19 Q. Is sunlight a Class 1 carcinogen? 20 A. Yes. 21 Q. Most of us are exposed to sunlight 22 every day, right? 23 MR. SLATER: Objection. 24 A. Unless you have xeroderma pigmentosa, 25 yes.</p>	<p style="text-align: right;">Page 147</p> <p>1 A. It is, but you have to think about -- 2 you have to read the preamble and, you know, dose 3 is part of the picture, so you have to take that 4 into account. When they say something is group 5 one, they're not talking -- they're not talking 6 about dose specifically. They're not talking 7 about other dose that you might get when you have 8 bacon. They're saying that, you know, processed 9 meat, consumption of processed meat can cause 10 cancer in humans. 11 Q. Sure. 12 It's known to cause cancer in humans 13 according to IARC? 14 A. Yes, but they're not talking about 15 the amount of processed meat. They don't do that. 16 Q. Everything is dose dependent? 17 MR. SLATER: Objection. 18 You can answer. 19 A. Most are. But, you know, the way you 20 just stated this thing, it sounded like you 21 weren't taking dose into account. The statement 22 that, you know, that you made a couple minutes ago 23 when you first brought up processed meat that -- 24 you said something like "The bacon that I enjoy 25 for breakfast is a group one carcinogen." Yeah,</p>
<p style="text-align: right;">Page 146</p> <p>1 Q. Most of us don't? 2 A. Correct. 3 Q. But most of us are exposed to 4 sunlight, a known human carcinogen, on a daily 5 basis, right? 6 A. Yes. 7 Q. Processed meat, I think, is a Class 1 8 known carcinogen, right? 9 A. I don't know whether it's 1 or 2A. 10 Q. You're not sure about that one? 11 A. No. You can look on your list. 12 Q. Let me take a look. 13 Can you go to page 30, sir? 14 Highlight the top third of that page for the 15 witness. I think we can -- 16 According to Exhibit 10 from the IARC 17 monograph, processed meat is a group one -- 18 A. Group one. 19 Q. -- carcinogen, right? 20 A. Group one. Yes. 21 Q. So the bacon that I enjoy for 22 breakfast is a known carcinogen? 23 A. That would be a processed meat, yes. 24 Q. The deli meat that I have for lunch 25 is a known carcinogen, according to IARC?</p>	<p style="text-align: right;">Page 148</p> <p>1 that's true. But everything depends on dose. 2 Q. I couldn't agree with you more. 3 There are a lot of other foods and beverages that 4 we consume every day that are Class 1 and Class 2A 5 carcinogens according to IARC, correct? 6 A. Yes. 7 Q. The hot coffee or hot tea that we 8 enjoy in the morning is a carcinogen according to 9 IARC, right? 10 MR. SLATER: Objection. 11 You can answer. 12 A. I don't think so. 13 Q. Well, if we go to -- 14 A. Coffee? Coffee? 15 Q. Yes, that's what I said. Hot tea or 16 hot coffee. 17 A. They're talking about super heated. 18 There are certain areas in the world where very 19 hot beverages are consumed. It has nothing to do 20 with what you do. Those very hot beverages can 21 lead to cancer. 22 Q. Sure. Very hot -- 23 A. Has nothing to do with your cup of 24 coffee. 25 Q. Very hot beverages --</p>

<p style="text-align: right;">Page 149</p> <p>1 A. Not at all.</p> <p>2 Q. Very hot beverages above 65 degrees</p> <p>3 Celsius?</p> <p>4 A. I don't remember the temperature</p> <p>5 involved.</p> <p>6 Q. How does 65 --</p> <p>7 A. I think it's higher than that.</p> <p>8 Q. How does 65 degrees Celsius convert</p> <p>9 to Fahrenheit?</p> <p>10 A. Nine fifth C plus 32. You do the</p> <p>11 math.</p> <p>12 Q. I will.</p> <p>13 Are fried foods a known carcinogen</p> <p>14 according to IARC?</p> <p>15 A. Look on the list.</p> <p>16 Q. I'm asking you if you know. I will.</p> <p>17 But do you know?</p> <p>18 A. I haven't memorized the list. I told</p> <p>19 you that.</p> <p>20 MR. TRISCHLER: Go to page -- I'll</p> <p>21 come back to it because I can't find it right</p> <p>22 now.</p> <p>23 Q. Is it fair to say that according to</p> <p>24 IARC most of us are exposed to known and probably</p> <p>25 carcinogens on a daily basis?</p>	<p style="text-align: right;">Page 151</p> <p>1 MR. SLATER: Objection.</p> <p>2 A. It's challenging. Definitely</p> <p>3 challenging, but there are examples. I think I</p> <p>4 mentioned one earlier where sunlight can cause a</p> <p>5 cross linking of thymidines in DNA in individuals</p> <p>6 who cannot repair that damage. It's a specific</p> <p>7 disease called xeroderma pigmentosa. Those</p> <p>8 individuals are exposed at all to sunlight, they</p> <p>9 get skin tumors. So yes.</p> <p>10 Q. Are you suggesting that -- it sounds</p> <p>11 like what you're suggesting is that sunlight can</p> <p>12 cause unique mutations?</p> <p>13 A. Yes.</p> <p>14 Q. Absent that example, when we talk</p> <p>15 about environmental exposures, do you have the</p> <p>16 ability to look at a given case and sort out</p> <p>17 multiple carcinogenic exposures and identify one</p> <p>18 as the cause of cancer in any given case?</p> <p>19 MR. SLATER: Objection.</p> <p>20 You can answer.</p> <p>21 A. Sure. An example would be smokeless</p> <p>22 tobacco. I can identify exposure to an oral</p> <p>23 cavity, oral mucosa carcinogen in smokeless</p> <p>24 tobacco.</p> <p>25 Q. Is there any such thing as a</p>
<p style="text-align: right;">Page 150</p> <p>1 A. I don't think IARC ever said that.</p> <p>2 I'm not aware that IARC ever made a statement like</p> <p>3 that.</p> <p>4 Q. Let me rephrase the question.</p> <p>5 Based on the IARC classifications of</p> <p>6 agents, would you agree that most of us are</p> <p>7 exposed to known and probable carcinogens on a</p> <p>8 daily basis?</p> <p>9 A. Well, we don't need IARC for that. I</p> <p>10 mean, you know, sunlight -- again, it's all in the</p> <p>11 dose. Everything is dependent on dose.</p> <p>12 Q. In our lifetime, all of us are going</p> <p>13 to be exposed to dozens of carcinogens; true?</p> <p>14 A. I wouldn't say necessarily dozens,</p> <p>15 but yes, we're all exposed to carcinogens, yes. I</p> <p>16 don't know about dozens. I don't know. I'm not</p> <p>17 sure what that means.</p> <p>18 Q. How about multiple? Would you agree</p> <p>19 that all of us during our lifetime are exposed to</p> <p>20 multiple carcinogens?</p> <p>21 A. Yes, multiple means more than one.</p> <p>22 Q. So when an individual has a lifetime</p> <p>23 exposure to multiple carcinogens, do you have the</p> <p>24 basis or ability to determine the cause of cancer</p> <p>25 in any individual case?</p>	<p style="text-align: right;">Page 152</p> <p>1 signature genetic lesion associated with NDMA?</p> <p>2 A. There is a signature genetic lesion,</p> <p>3 whether that would be associated with NDMA, but</p> <p>4 there might also be other causes. So</p> <p>5 O6-methylguanine is a signature genetic lesion, a</p> <p>6 mutation in the KRAS gene, G28 transition in the</p> <p>7 second base of codon 12. That's a signature that</p> <p>8 comes from O6-methylguanine. So yes, that's a</p> <p>9 signature mutation. Doesn't necessarily come from</p> <p>10 dimethylnitrosamine as opposed to perhaps another</p> <p>11 DNA methylating agent. We don't know. But that</p> <p>12 would be a signature mutation.</p> <p>13 Another example is in the P53 tumor</p> <p>14 suppressor gene where it's been shown that</p> <p>15 benzoapyrene and some other polycyclic aromatic</p> <p>16 hydrocarbons as well as acrolein can cause</p> <p>17 mutations at certain specific codons of the P53</p> <p>18 tumor suppressor gene.</p> <p>19 Those would qualify as signature</p> <p>20 mutations. So yes, there are other examples other</p> <p>21 than the thymidine cross links that I mentioned</p> <p>22 earlier. So there are examples.</p> <p>23 Q. Maybe my question wasn't 100% clear.</p> <p>24 When I was using the term "signature</p> <p>25 genetic lesions," what I was referring to were</p>

<p style="text-align: right;">Page 153</p> <p>1 lesions that would be unique to NDMA as opposed to 2 other potential sources and it sounds like when 3 you mentioned the P53 tumor, the O6-methylguanine 4 and the KRAS gene, those lesions may be the 5 result -- may be consistent with NDMA, but they 6 might also be consistent with other causes? 7 A. That's possible. 8 Q. Right. So my question -- 9 A. But you know, everything has to be 10 taken in context. So, you know, I think valsartan 11 would be a good example of a study that could be 12 done to identify such a genetic mutation that was 13 caused by an NDMA. 14 Q. But until that study is done, we 15 can't say that the lesion is specifically caused 16 by or related to DNA absent that scientific study? 17 MR. SLATER: Objection. 18 A. Related to what? 19 Q. I misspoke. I'm sorry. 20 Absent that study and until such a 21 study is done, we don't have the scientific 22 ability to look at a particular lesion and say it 23 was definitively caused by NDMA exposure? 24 MR. SLATER: Objection. 25 You can answer.</p>	<p style="text-align: right;">Page 155</p> <p>1 your report, and I think you alluded to it a 2 little bit earlier, is that you served as a 3 panelist in an FDA workshop in 2021, right? 4 A. Correct. 5 Q. I think that workshop was in March of 6 this year; true? 7 A. Yes. 8 Q. And at the time you attended that and 9 participated in that FDA workshop, you were an 10 active consultant for the plaintiffs in this 11 litigation; true? 12 A. Yes. 13 Q. You'd already been hired by 14 Mr. Slater over a year and a half ago? 15 A. Right. 16 Q. How did your involvement in this FDA 17 workshop come to be? 18 A. They contacted me and asked me 19 whether because of my extensive experience and 20 knowledge of nitrosamine carcinogenicity whether I 21 would like to participate. 22 Q. When you say they contacted you, are 23 you referring to someone at the FDA? 24 A. Yes. 25 Q. Who might that have been?</p>
<p style="text-align: right;">Page 154</p> <p>1 A. No, not right now. We don't have the 2 data. The study should be done. 3 Q. I asked before about NDMA. 4 Are you aware of whether there's any 5 such thing as a signature genetic lesion 6 associated with NDEA? 7 A. NDEA would produce the same kind of 8 lesion in DNA O6-methylguanine, which could lead 9 to G2A transitions in codon 12. 10 Q. What is that -- 11 A. But I think there's less data for an 12 ethylating agent, but you would certainly expect 13 the same, the same thing. 14 Q. What is that opinion based on? 15 A. My knowledge of the scientific 16 literature. 17 Q. Is there scientific literature that 18 specifically describes the type of DNA changes 19 that one sees in humans from NDEA? 20 A. Not in humans. 21 Q. Following the discovery of 22 nitrosamines in some medications, you've been 23 involved in working with the FDA, correct? 24 A. Yes. 25 Q. One of the things you mentioned in</p>	<p style="text-align: right;">Page 156</p> <p>1 A. I really don't remember. I could dig 2 out the email if you really want to find out, if 3 you want me to. I don't remember the person's 4 name, but definitely they had contacted me. 5 They said there's going to be a 6 workshop on whatever the dates were and we're 7 planning the workshop and we'd like you to 8 participate as a panelist or discussant. I can 9 provide the email if you want. 10 Q. When you were approached by the FDA 11 to serve on this panel, did you disclose to them 12 your potential bias given your involvement in this 13 litigation? 14 MR. SLATER: Objection. 15 You can answer. 16 A. No, I don't believe I have a bias. I 17 don't have a bias. Definitely not. There's no 18 bias here. It's all based on science. 19 Q. All right. 20 A. I don't know why you bring up bias. 21 Q. Because I'm asking -- 22 A. Why would you do that? 23 Q. Because I'm asking questions, sir. 24 A. Okay. 25 Q. Did you disclose --</p>

<p style="text-align: right;">Page 157</p> <p>1 A. Okay. I'm saying I don't have any 2 bias. 3 Q. You said that six times, so let me 4 ask my next question. 5 A. So I want to make sure you understand 6 it. 7 Q. Did you disclose to the FDA that you 8 were working on behalf of the plaintiffs pursuing 9 claims against drug companies? 10 MR. SLATER: Objection. 11 You can answer. 12 A. I honestly don't remember. I may 13 have. I really don't remember. 14 Q. Do you have email correspondence 15 where you told them that? 16 A. I have email correspondence. Whether 17 I told them that or not, I really don't know. 18 Q. I think you were one of, like, 16 -- 19 A. I wouldn't consider it a conflict of 20 interest at all. 21 Q. I think you were one of, like, 16 22 members of this panel, right? 23 A. Yeah, that's right. 24 Q. Was it a group of esteemed experts in 25 their field?</p>	<p style="text-align: right;">Page 159</p> <p>1 A. Yes. 2 MR. TRISCHLER: For instance -- why 3 don't we mark as Exhibit 11 this document 4 entitled "Information about Nitrosamine 5 Impurities in Medications" that comes from 6 the FDA website? 7 Can you mark that, Bill? 8 THE VIDEOGRAPHER: Sure thing. Just 9 looking for it now. 10 (Whereupon, Exhibit 11 was marked for 11 identification.) 12 Q. What you're looking at now is an 13 eight-page document from the FDA website. 14 Is this one of the things you read -- 15 do you know if this was one of the things you read 16 in connection with your work in this case? 17 A. I don't recall this. 18 Q. Can you go to page four of the 19 exhibit, sir? The last section has a number of 20 bullet points. Thank you. 21 I don't know that this is page four 22 that you have. At least it's not page four of 23 mine. 24 THE VIDEOGRAPHER: What are you 25 looking for on the page? This is page four</p>
<p style="text-align: right;">Page 158</p> <p>1 A. Yes. 2 Q. A group of well-respected scientists 3 whose opinions you value and trust? 4 A. Yes. 5 Q. In addition to this workshop that you 6 participated in with the FDA, were you also aware 7 that the FDA has issued a number of public 8 statements concerning the nitrosamine impurities 9 found in drug products? 10 A. Yes. 11 Q. You've mentioned one of the things 12 you did in your work in this case was to look into 13 the public data and public information that was 14 available on that, right? 15 A. Yes. 16 Q. So you were certainly aware that the 17 FDA has made lots of public statements about the 18 nitrosamine impurities and the significance of 19 those impurities, correct? 20 A. As well they should. 21 Q. In those public statements, is it 22 true that FDA has consistently observed and 23 reported to the public that the theoretical risk 24 of harm from nitrosamines in medications is 25 extremely low?</p>	<p style="text-align: right;">Page 160</p> <p>1 for me? 2 MR. TRISCHLER: Top of the page says 3 "What you should know about nitrosamine 4 impurities." It's the middle box. I'm 5 sorry. There we go. Yes. Okay. Sorry. 6 Different printing. 7 Q. You can see in the middle of the 8 page -- I think it's the fourth bullet point that 9 we've expanded -- that reads "Nitrosamine 10 impurities may increase the risk of cancer if 11 people are exposed to them above acceptable levels 12 and over long periods of time, but a person taking 13 a dose that contains nitrosamines at or below 14 acceptable daily intake limits every day for 70 15 years is not expected to have an increased risk of 16 cancer." 17 Do you see that statement? 18 A. Yes. 19 Q. Do you agree with it, sir? 20 A. Well, I thought that they had come 21 out with a risk estimate. I've forgotten the 22 exact number. So I'm a little confused by this 23 particular statement. I'm not quite sure what 24 they mean, "not expected to have an increased risk 25 of cancer." It's a little confusing.</p>

<p style="text-align: right;">Page 161</p> <p>1 Q. It seems to me what they're saying is</p> <p>2 at low levels, they would not expect nitrosamines</p> <p>3 in valsartan medications to cause an increased</p> <p>4 risk of cancer.</p> <p>5 Do you agree or disagree?</p> <p>6 MR. SLATER: Objection.</p> <p>7 You can answer.</p> <p>8 A. Well, I'm pretty sure they -- I don't</p> <p>9 know whether it was after this or -- I'm pretty</p> <p>10 sure they came out actually with a risk estimate</p> <p>11 of something like a one in 7,000 or something like</p> <p>12 that. So I don't know how that relates to this</p> <p>13 exactly, but I know that they -- their position</p> <p>14 was that the risk was low. So I'm aware of that.</p> <p>15 Q. Let's start with that.</p> <p>16 You said you're aware that the FDA's</p> <p>17 position that the risk of nitrosamines in</p> <p>18 valsartan-containing medications containing was</p> <p>19 low.</p> <p>20 Do you agree with that statement?</p> <p>21 MR. SLATER: Objection.</p> <p>22 You can answer.</p> <p>23 A. It was low compared to the benefit of</p> <p>24 the medication. So they recognize the fact that</p> <p>25 the medications are effective and that they are</p>	<p style="text-align: right;">Page 163</p> <p>1 was prepared after the FDA had done a risk</p> <p>2 assessment on the relative risk presented by</p> <p>3 nitrosamine impurities?</p> <p>4 A. Yeah, I'm not sure exactly about this</p> <p>5 statement -- okay? -- because I thought -- maybe</p> <p>6 I'm wrong here, but as I recall, FDA actually came</p> <p>7 out with a number based on a risk assessment</p> <p>8 exercise that was something like, you know, one in</p> <p>9 9,000 or something like that. So I'm a little</p> <p>10 confused by this statement. I did not expect it.</p> <p>11 I'm not sure what it means, not expected to have</p> <p>12 an increased risk of cancer.</p> <p>13 Q. Well, if the words --</p> <p>14 A. What does that mean exactly, "not</p> <p>15 expected to"? I don't understand that.</p> <p>16 Q. If the words "not expected" are</p> <p>17 troubling to you, I'll withdraw the question. Let</p> <p>18 me ask you something different.</p> <p>19 Have you conducted an independent</p> <p>20 risk assessment related to nitrosamine exposure</p> <p>21 from valsartan-containing medications?</p> <p>22 A. No, I have not.</p> <p>23 Q. Do you understand that regulatory</p> <p>24 limits for acceptable daily intake have been</p> <p>25 established by FDA?</p>
<p style="text-align: right;">Page 162</p> <p>1 useful drugs and as I understand it, their</p> <p>2 position was that, you know, even though this</p> <p>3 horrible contamination has happened and, you know,</p> <p>4 it never should have happened, never would have</p> <p>5 been approved in any way whatsoever, but these</p> <p>6 drugs have been approved by FDA, if they had been</p> <p>7 known to contain dimethyl and dimethylnitrosamine,</p> <p>8 there's no way they would ever be approved, but</p> <p>9 the fact that it did happen and the drugs are out</p> <p>10 there now in the market, they were trying to tell</p> <p>11 people that don't stop taking your drug right now</p> <p>12 because, you know, that could have worse</p> <p>13 consequences than the nitrosamines. That's how I</p> <p>14 understand it.</p> <p>15 MR. TRISCHLER: Object and move to</p> <p>16 strike as non-responsive.</p> <p>17 Q. Let's look at the sentence that's up</p> <p>18 on the screen.</p> <p>19 Do you agree with the statement that</p> <p>20 a person taking a drug that contains nitrosamines</p> <p>21 at or below the acceptable daily intake limits</p> <p>22 every day for 70 years is not expected to have an</p> <p>23 increased risk of cancer?</p> <p>24 A. No.</p> <p>25 Q. Do you realize that this statement</p>	<p style="text-align: right;">Page 164</p> <p>1 A. I'm not sure how to answer that. I</p> <p>2 thought that they came up with a 96 nanograms per</p> <p>3 day. That's what they came up with, that</p> <p>4 96 nanograms per day would be acceptable. Above</p> <p>5 that would not be.</p> <p>6 Q. Right. That was my question.</p> <p>7 Based on its risk assessment, the FDA</p> <p>8 established that an acceptable daily intake of</p> <p>9 NDMA was 96 nanograms per day.</p> <p>10 You're familiar with that, right?</p> <p>11 A. Yes, that's what I said.</p> <p>12 Q. Based on FDA's risk assessment, it</p> <p>13 was -- they determined an acceptable daily intake</p> <p>14 of 26.5 nanograms per day was acceptable for NDEA,</p> <p>15 right?</p> <p>16 A. Yes.</p> <p>17 Q. You understood that those acceptable</p> <p>18 daily intake numbers were based on a lifetime</p> <p>19 exposure of 70 years, correct?</p> <p>20 A. Yes, that's how they did the</p> <p>21 calculation.</p> <p>22 Q. So if you do the math for NDMA, 96</p> <p>23 times 365 times 70 leaves a lifetime acceptable</p> <p>24 exposure limit, according to FDA, of</p> <p>25 2.5 million nanograms, right, plus change?</p>

<p style="text-align: right;">Page 165</p> <p>1 A. You did it, not me.</p> <p>2 Q. A lifetime acceptable limit of NDEA</p> <p>3 according to FDA's risk assessment would be 26.5</p> <p>4 times 365 times 70, right?</p> <p>5 A. Yes.</p> <p>6 Q. And you understand, I assume, that no</p> <p>7 plaintiff in this case was taking nitrosamines</p> <p>8 containing -- nitrosamine-containing medications</p> <p>9 for 70 years or anything close to that, right?</p> <p>10 A. Probably not.</p> <p>11 Q. And what FDA said in its risk</p> <p>12 assessment was that exposure to roughly two and a</p> <p>13 half million nanograms of NDMA was reasonably safe</p> <p>14 for human consumption, right?</p> <p>15 A. Yes.</p> <p>16 Q. That's what a risk assessment is?</p> <p>17 A. Yes.</p> <p>18 Q. Do you agree with that risk</p> <p>19 assessment?</p> <p>20 A. Yes, I agree with it. I mean, it's</p> <p>21 not really my area. I don't present myself as an</p> <p>22 expert in risk assessment or the calculation of</p> <p>23 risk. I don't do that. But I think it's</p> <p>24 reasonable what they did, what they came up with.</p> <p>25 It sounds reasonable to me.</p>	<p style="text-align: right;">Page 167</p> <p>1 day, sir.</p> <p>2 We're talking about causation here.</p> <p>3 MR. SLATER: Objection.</p> <p>4 Argumentative.</p> <p>5 Q. Excuse me.</p> <p>6 What the FDA said is that two and a</p> <p>7 half million nanograms of NDMA are reasonably safe</p> <p>8 for human consumption based on its risk assessment</p> <p>9 and you've not done any other assessment to say</p> <p>10 otherwise; true?</p> <p>11 MR. SLATER: Objection.</p> <p>12 Lack of foundation.</p> <p>13 You can answer.</p> <p>14 A. It's not what I do. That's true. I</p> <p>15 haven't done -- I haven't made any calculations.</p> <p>16 That's up to FDA, EMA and the risk assessors.</p> <p>17 That's not what I do.</p> <p>18 Q. What the FDA has said is that</p> <p>19 677,075 nanograms of NDEA is reasonably safe for</p> <p>20 human consumption and you've not done any</p> <p>21 alternative risk assessment to suggest otherwise?</p> <p>22 A. Correct.</p> <p>23 Q. When you sat in on the FDA</p> <p>24 nitrosamine workshop in March of this year, did</p> <p>25 you publically express any disagreement with FDA's</p>
<p style="text-align: right;">Page 166</p> <p>1 Q. But you do suggest, at least through</p> <p>2 your report, that you believe that nitrosamines in</p> <p>3 valsartan-containing medication increase the risk</p> <p>4 of causing cancer, right?</p> <p>5 A. Yes, absolutely.</p> <p>6 Q. And you told me that everything is</p> <p>7 dose and duration dependent, right?</p> <p>8 A. Yes.</p> <p>9 MR. SLATER: Objection.</p> <p>10 Q. So you need to know if you're going</p> <p>11 to have an opinion that an exposure increased the</p> <p>12 risk of causing cancer, you need to know what a</p> <p>13 reasonably safe level for human consumption is,</p> <p>14 right?</p> <p>15 MR. SLATER: Objection.</p> <p>16 You can answer.</p> <p>17 A. The safe level is zero. That's what</p> <p>18 it should be.</p> <p>19 Q. That's not what -- not according to</p> <p>20 the FDA.</p> <p>21 A. Well, that's okay. There's no way</p> <p>22 there should be NDMA or NDEA in these drugs. It</p> <p>23 should be zero. Absolutely.</p> <p>24 MR. TRISCHLER: Object and move to</p> <p>25 strike because those are issues for another</p>	<p style="text-align: right;">Page 168</p> <p>1 risk calculation?</p> <p>2 A. No.</p> <p>3 MR. SLATER: Objection.</p> <p>4 Lack of foundation.</p> <p>5 Q. That conference was over the course</p> <p>6 of two days, correct?</p> <p>7 A. Yes.</p> <p>8 Q. So if you had disagreement with FDA's</p> <p>9 risk calculation, you certainly had plenty of time</p> <p>10 to offer it, right?</p> <p>11 MR. SLATER: Objection.</p> <p>12 A. Sure, but as I recall -- I don't</p> <p>13 really remember. I don't think the -- this</p> <p>14 particular -- I don't remember whether, you know,</p> <p>15 the risk calculation was actually discussed at the</p> <p>16 workshop. I really don't remember.</p> <p>17 Q. Well, certainly --</p> <p>18 A. The workshop wasn't specifically --</p> <p>19 it was more general -- about nitrosamine exposure</p> <p>20 and carcinogenicity. Obviously, it related to</p> <p>21 drugs because that's what they do, but I don't</p> <p>22 really remember whether the risk calculation was</p> <p>23 actually discussed at that workshop. I don't</p> <p>24 think it was.</p> <p>25 Q. Well, you've already told me that you</p>

<p style="text-align: right;">Page 169</p> <p>1 are aware that the FDA, as the agency responsible</p> <p>2 for drug safety in America, has repeatedly made</p> <p>3 public statements that the health risk from</p> <p>4 nitrosamine impurities was very low.</p> <p>5 Do you remember telling me that?</p> <p>6 A. Yes.</p> <p>7 Q. And the workshop that you attended in</p> <p>8 March, there was actually a transcript prepared of</p> <p>9 the whole thing.</p> <p>10 Were you aware of that?</p> <p>11 A. Yes, I'm aware.</p> <p>12 Q. Do you have a copy of the transcript?</p> <p>13 A. No. Well, it might be on my</p> <p>14 computer. I don't have a hard copy. Not here</p> <p>15 with me, no.</p> <p>16 Q. Have you ever reviewed a transcript</p> <p>17 of the FDA workshop when you came back after it</p> <p>18 was completed in March?</p> <p>19 A. I did review it, yes.</p> <p>20 Q. And it was certainly discussed during</p> <p>21 the workshop, on multiple occasions, the fact that</p> <p>22 the risk from exposure to nitrosamine in</p> <p>23 valsartan-containing medications was de minimis.</p> <p>24 That was clearly discussed, correct?</p> <p>25 MR. SLATER: Objection.</p>	<p style="text-align: right;">Page 171</p> <p>1 and you did nothing about it.</p> <p>2 Agreed?</p> <p>3 MR. SLATER: Objection.</p> <p>4 Lack of foundation.</p> <p>5 Complete mischaracterization of what</p> <p>6 went on.</p> <p>7 You can answer.</p> <p>8 A. I think I already told you, I don't</p> <p>9 do risk assessment, so, you know, I wouldn't argue</p> <p>10 with the FDA's risk calculation. I already told</p> <p>11 you that, so why do you keep asking?</p> <p>12 Q. I'm trying to get an answer to my</p> <p>13 question.</p> <p>14 Did you tell anyone at FDA --</p> <p>15 MR. SLATER: Counsel, one second.</p> <p>16 Counsel, he's answered the question</p> <p>17 multiple times. You're beyond the point of</p> <p>18 arguing with him.</p> <p>19 Is there some other area you want to</p> <p>20 ask him questions about --</p> <p>21 Q. Did you tell anybody --</p> <p>22 MR. SLATER: -- or do you want to</p> <p>23 pull the transcript out or show us the</p> <p>24 question or do you want to pull the</p> <p>25 transcript out and try to find a question</p>
<p style="text-align: right;">Page 170</p> <p>1 You can answer.</p> <p>2 A. Yes.</p> <p>3 Q. When you were sitting there for two</p> <p>4 days, did you ever express to anyone on that panel</p> <p>5 your disagreement with that belief?</p> <p>6 A. No.</p> <p>7 Q. Did you tell anyone that FDA during</p> <p>8 this two-day panel that they were wrong, that the</p> <p>9 risk of developing cancer from these small amounts</p> <p>10 of nitrosamines was actually much larger than that</p> <p>11 they believed?</p> <p>12 MR. SLATER: Objection.</p> <p>13 You can answer.</p> <p>14 A. No, I told you that's not what I do.</p> <p>15 I don't do risk assessment calculations, so I</p> <p>16 would have no grounds to do that, to say that and</p> <p>17 I'm not disagreeing with the risk assessment</p> <p>18 calculations that are out there.</p> <p>19 Q. Okay.</p> <p>20 A. That's not what I do, so why would I</p> <p>21 say something like that?</p> <p>22 Q. My point is that you had an</p> <p>23 opportunity in March to tell the FDA that their</p> <p>24 assessment of the risk of nitrosamine impurities</p> <p>25 in drugs being anything but de minimis was wrong</p>	<p style="text-align: right;">Page 172</p> <p>1 that actually asks that question?</p> <p>2 I'll be happy to wait for you to look</p> <p>3 for that in the transcript.</p> <p>4 Q. Did you tell anyone at FDA their risk</p> <p>5 assessment was wrong? Yes or no?</p> <p>6 A. No.</p> <p>7 Q. Although you don't -- although you</p> <p>8 say risk assessments are not your business, are</p> <p>9 you aware of the fact that risk assessments, when</p> <p>10 they're performed by regulatory agencies, are</p> <p>11 intended to be extremely conservative so as to</p> <p>12 decide a patient's safety?</p> <p>13 A. Yes.</p> <p>14 Q. Would you agree that the</p> <p>15 establishment of a conservative, acceptable intake</p> <p>16 limit does not imply that an exposure at a higher</p> <p>17 level can cause harm?</p> <p>18 MR. SLATER: Objection.</p> <p>19 A. I'm not sure I understand your</p> <p>20 question.</p> <p>21 Q. Based on what you know about risk</p> <p>22 assessments, would you agree that it is generally</p> <p>23 known and understood that those -- the</p> <p>24 establishment of those conservative estimates does</p> <p>25 not mean that an exposure at levels above what's</p>

<p style="text-align: right;">Page 173</p> <p>1 determined to be an acceptable level will</p> <p>2 necessarily cause harm?</p> <p>3 MR. SLATER: Objection.</p> <p>4 You can answer.</p> <p>5 A. Correct. It's based on the</p> <p>6 probability.</p> <p>7 Q. And in fact --</p> <p>8 A. It's all based on probability</p> <p>9 calculations.</p> <p>10 Q. In fact, in some of the research that</p> <p>11 you cited in your report that you prepared in this</p> <p>12 case, you identified evidence and provided us with</p> <p>13 information suggesting that virtually all of us</p> <p>14 are exposed to NDMA and NDEA on a daily basis at</p> <p>15 concentrations far greater than the acceptable</p> <p>16 intakes established by FDA, right?</p> <p>17 A. I don't know about "far greater." We</p> <p>18 are all exposed through the diet for sure.</p> <p>19 Q. Okay.</p> <p>20 A. I don't know about "far greater."</p> <p>21 That depends on your diet, that depends on</p> <p>22 concentrations of NDMA and NDEA and the various</p> <p>23 foods that you eat and drinking water, etc. So I</p> <p>24 don't know about "far greater."</p> <p>25 (Whereupon, Exhibit 12 was marked for</p>	<p style="text-align: right;">Page 175</p> <p>1 Q. Okay.</p> <p>2 A. Then you know there's the question of</p> <p>3 whether it's nitrosamines in general or</p> <p>4 specifically tobacco specific nitrosamines</p> <p>5 or dimethylnitrosamine. I'd have to go back and</p> <p>6 look at that. So I'm not sure about that number</p> <p>7 you just gave me.</p> <p>8 Q. Well, let's go --</p> <p>9 A. Because the levels of</p> <p>10 dimethylnitrosamine in a cigarette are actually</p> <p>11 quite low.</p> <p>12 Q. Well, you can certainly --</p> <p>13 A. He was talking about nitrosamines in</p> <p>14 general, so that would include tobacco specific</p> <p>15 nitrosamines, which are present in higher</p> <p>16 concentrations. So I think that's where he got</p> <p>17 the tobacco part in his pie chart or whatever it</p> <p>18 was.</p> <p>19 Q. Let's go to page 1130 of this Exhibit</p> <p>20 number 12, please. It's the last paragraph on the</p> <p>21 right-hand side.</p> <p>22 One of the things Dr. Gushgari did</p> <p>23 was to estimate nitrosamine intake and nitrosamine</p> <p>24 exposure for all of us, correct?</p> <p>25 A. Yes.</p>
<p style="text-align: right;">Page 174</p> <p>1 identification.)</p> <p>2 Q. Let's take a look at the paper that</p> <p>3 you cited in your report from Gushgari,</p> <p>4 G-U-S-H-G-A-R-I. I think it's entitled "Critical</p> <p>5 Review of Major Sources of Human Exposure to</p> <p>6 Nitrosamines."</p> <p>7 Do you recall this paper, Dr. Hecht?</p> <p>8 A. Yes.</p> <p>9 Q. Was my representation correct, that</p> <p>10 this was indeed a paper that you cited in your</p> <p>11 report that you prepared in this case?</p> <p>12 A. It is, yes.</p> <p>13 Q. And in Gushgari, the authors</p> <p>14 concluded that some Americans ingest as much as</p> <p>15 25,000 to 30,000 nanograms of nitrosamines every</p> <p>16 single day, correct?</p> <p>17 A. That's with respect to tobacco use, I</p> <p>18 believe.</p> <p>19 Q. Right.</p> <p>20 So smokers, according to Gushgari,</p> <p>21 consume on the order of 25,000 to 30,000 nanograms</p> <p>22 of nitrosamines every day?</p> <p>23 A. I'm not sure whether he means smokers</p> <p>24 or smokeless tobacco users. I'd have to look at</p> <p>25 that.</p>	<p style="text-align: right;">Page 176</p> <p>1 Q. And what he said was that if you --</p> <p>2 if tobacco use -- if you're a smoker, the rate of</p> <p>3 your nitrosamine intake is on the order of 21,800</p> <p>4 plus or minus 4,350 nanograms per day, right?</p> <p>5 A. I don't think it also includes</p> <p>6 smokers. I think it's smokeless tobacco users.</p> <p>7 Q. Understood.</p> <p>8 But what he discusses in this paper</p> <p>9 is that in addition to tobacco, our diet is also a</p> <p>10 source of nitrosamines, correct?</p> <p>11 A. Correct.</p> <p>12 Q. According to Gushgari, depending on</p> <p>13 what you eat, you'll consume between 1,800 to</p> <p>14 1,900 nanograms of nitrosamine from your food,</p> <p>15 right?</p> <p>16 A. That's what he came up with, right.</p> <p>17 Q. Beer was another -- if you go to page</p> <p>18 1131, I think beer was also a source of -- or</p> <p>19 potential source -- of nitrosamines according to</p> <p>20 Gushgari on the order of 1,000 nanograms per day,</p> <p>21 right?</p> <p>22 A. Mm-hmm. Yeah.</p> <p>23 Q. He also noted that water was a source</p> <p>24 of nitrosamines on the order of about</p> <p>25 120 nanograms per day?</p>

<p style="text-align: right;">Page 177</p> <p>1 A. Yeah, I don't know if that's -- I'm 2 not sure about that number. Water is very low. 3 Q. It says -- it was highlighted. 4 Can you highlight it again, please? 5 According to the paper here, the 6 nitrosamine exposure from water is about 7 120 nanograms per day, right? 8 A. Yeah, but I'm not sure -- there's 9 some problems with -- there's some measurement 10 problems with the order story having to do with 11 artifact formation of NDMA during analysis. So 12 I'm not sure. I don't recall whether his water 13 calculation I think was -- may have been carried 14 out before some of those analytical chemistry 15 problems came to light. So I'm not sure about the 16 water. I have to look at that more carefully. 17 Q. This study was done in 2018, right? 18 A. The review was published in 2018. 19 Q. Correct. 20 A. I don't know whether all of the water 21 literature that he considered was before the 22 finding that some of the water measurements were 23 wrong. I don't know offhand. 24 Q. So what you're suggesting to me -- 25 what you're suggesting to me --</p>	<p style="text-align: right;">Page 179</p> <p>1 according to Gushgari, those individuals are going 2 to be exposed to daily levels of nitrosamines on 3 the order of about 2,000 nanograms per day, right? 4 A. From food. Food and water, I guess, 5 and beer. I don't know. The 2,000 is just from 6 food or is it 2,000 from food plus beer plus 7 water? 8 Q. Beer is separate. That's why I left 9 it out. 10 A. Yeah. So what is it just from food? 11 Q. It says -- right in the first line 12 that you're looking at here on the exhibit, 1,800 13 plus or minus 350 for a vegetarian diet, 1,900 14 plus or minus 380 for a Western diet. 15 A. Okay. 16 Q. So I was using 2,000 as a round 17 number. 18 A. Okay. 19 Q. In your report, you suggest that you 20 received information about nitrosamine levels 21 observed in the valsartan-containing products of 22 some of the defendants to this litigation, 23 correct? 24 A. Yes. 25 Q. One of the defendants is Mylan, who I</p>
<p style="text-align: right;">Page 178</p> <p>1 A. I'm suggesting that the water might 2 be wrong. Everything else probably right. 3 Q. Might be lower than 120 nanograms? 4 A. Right. Yeah. 5 Q. I guess it would depend on the 6 quality of the water you drink, where you get it, 7 what the source is, right? 8 A. In part, but, I mean, the calculation 9 would have to be redone based on the actual data. 10 That's not -- that doesn't have artifacts in it. 11 Q. Well, so let's take water out of the 12 equation because you said the other numbers from 13 Gushgari are probably right. 14 So what his paper suggests to us is 15 that individuals who are exposed to tobacco will 16 consume around 25,000 nanograms of nitrosamines 17 every single day of their life, right? 18 A. No, not exposed to tobacco. Use 19 tobacco. There's a difference. 20 Q. Individuals who use tobacco will be 21 exposed to 25,000 nanograms of nitrosamine every 22 day, right? 23 A. That's what he came up with, yes. 24 Q. For those non-smokers and 25 non-drinkers who lead a good, healthy life,</p>	<p style="text-align: right;">Page 180</p> <p>1 identified for you before as a company that I'm 2 representing. You heard of that name before and 3 you reviewed some of their data, correct? 4 A. Yes. 5 Q. If I could just direct your attention 6 just for a second to -- I think it's page 24 and 7 25 of your report. 8 One of the things you indicate on 9 pages 24 and 25 of your report is you had the 10 opportunity to review information relating to 11 nitrosamine levels that were observed in Mylan 12 product, right? 13 A. Yes. 14 Q. On page 25, the first full paragraph, 15 you write that Mylan's API testing confirmed NDEA 16 levels in API batches ranging from 0.1 parts per 17 million to 1.57 parts per million. 18 Did I read that accurately from your 19 report? 20 A. Yes. 21 Q. As part of your work in this case, 22 sir, did you take that data and attempt to 23 calculate a mean NDEA concentration for Mylan's 24 valsartan? 25 A. No, I did not.</p>

<p style="text-align: right;">Page 181</p> <p>1 Q. I'll represent to you that the mean 2 is 0.47 parts per million for all batches tested 3 and I'll ask you to accept that number for 4 purposes of my next question. 5 Okay? 6 A. Okay. 7 MR. SLATER: Objection. 8 You can answer. 9 Q. If you know the parts per million of 10 a nitrosamine, you can convert that to nanograms 11 by multiplying it by the dose, right? 12 A. Yes. 13 Q. In fact, you've done -- you did that 14 calculation in various parts of your report? 15 A. Yes. 16 Q. So if we assume an NDEA concentration 17 at the mean of 0.47 parts per million and multiply 18 it by the highest possible dose, 300 micrograms of 19 valsartan, we get a nanogram of about 20 150 nanograms per day, correct? 21 A. Okay. 22 Q. 0.47 times 320? 23 A. Okay. 24 Q. Do you agree that that math comes out 25 to about 150?</p>	<p style="text-align: right;">Page 183</p> <p>1 Q. If we assume an intake of 150 2 nanograms per day for Mylan's valsartan, that 3 clean-living individual has increased his or her 4 nitrosamine intake by about 7.5%, right? 5 A. Correct. 6 Q. So what I'd like to know, Dr. Hecht, 7 is what peer-reviewed scientific literature has 8 ever been published to suggest that a modest one 9 to seven percent increase in nitrosamine 10 concentrations over a limited period of time would 11 cause cancer in humans? 12 A. I'm not aware of any. 13 Q. In your report, you certainly don't 14 cite any research or studies that establish a one 15 to seven percent increase in baseline nitrosamine 16 consumption will lead to cancer in humans. 17 Do you? 18 MR. SLATER: Objection. 19 A. No. 20 Q. And you don't cite any because no 21 such data exists, right? 22 A. I didn't cite any. So if it existed, 23 I would have cited it. 24 Q. Right. 25 And the fact is that science hasn't</p>
<p style="text-align: right;">Page 182</p> <p>1 A. Sounds right, yeah. 2 Q. So taking the mean from my data of 3 about 0.47, what it tells us is that 4 hypothetically, a user of Mylan's valsartan may 5 have consumed an additional 150 nanograms per day 6 during the period he or she used the drug, right? 7 A. Right. Yes. 8 Q. So if we go back then to Gushgari's 9 numbers, we know that tobacco users have a daily 10 nitrosamine intake on the order of 11 25,000 nanograms, correct? 12 A. Is that his number? 13 Q. For tobacco users. 14 A. Yes. 15 Q. If we assume an intake now of 16 150 nanograms a day for Mylan's valsartan, that 17 individual has increased their daily nitrosamine 18 intake by a scant 0.6%, right? 19 A. Correct. 20 Q. If we take a non-smoker and a 21 non-drinker who is living right, Gushgari tells us 22 they will have exogenously consumed about 2,000 23 nanograms a day. 24 Do you see that highlighted? 25 A. Yes.</p>	<p style="text-align: right;">Page 184</p> <p>1 even advanced enough that the worldwide agencies 2 classify NDEA or NDMA as known human carcinogens, 3 right? They've never done that? 4 A. Well, I wouldn't say that exactly 5 because -- go back to my book here. It says that 6 it should be regarded for practical purposes as if 7 it were carcinogenic to humans, 1978. 1978, but 8 you're right. 9 Q. Right about what? 10 A. No one has said that 7.5% increase in 11 nitrosamine exposure would lead to cancers in 12 humans -- 13 Q. I think it's one o'clock -- 14 A. -- in the setting that you just 15 described. 16 Q. I think it's one o'clock. I'm 17 willing to keep going, but you had indicated you 18 wanted to take a break at one o'clock, Doctor. 19 Do you want to -- 20 A. My watch says 12:30. 21 Q. Okay. Let's keep going. 22 A. It's 12:30 here. 23 Q. Sorry. Let's keep going then. 24 So what we've been talking about so 25 far is that exogenous nitrosamine consumption,</p>

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<p>1 correct?</p> <p>2 A. Yes.</p> <p>3 Q. And when we talk about exogenous</p> <p>4 consumption, we mean nitrosamines formed outside</p> <p>5 the organism, right?</p> <p>6 A. Yes.</p> <p>7 Q. In this case, though, with respect to</p> <p>8 nitrosamines like NDMA and NDEA, we know that</p> <p>9 they're also formed endogenously, right?</p> <p>10 A. No, we don't really know that. We</p> <p>11 don't know that NDMA and NDEA are formed</p> <p>12 endogenously. We don't know that.</p> <p>13 Q. Huh. Well, have you seen research</p> <p>14 suggesting that endogenous formation of NDEA and</p> <p>15 NDMA and other nitrosamines are significant?</p> <p>16 A. Yes, I have seen such research and I</p> <p>17 believe it's wrong.</p> <p>18 Q. Well, tell me what research you've</p> <p>19 seen to suggest that NDMA and NDEA are not formed</p> <p>20 endogenously.</p> <p>21 A. I don't think that it's -- let's put</p> <p>22 it this way: It's hard to prove a negative. I</p> <p>23 can't cite any research that proves that they're</p> <p>24 not formed endogenously. We do know that there's</p> <p>25 very solid research that some nitroso compounds</p>	<p>1 in my opinion, there's no solid evidence for</p> <p>2 endogenous formation of NDMA and NDEA in humans.</p> <p>3 There are studies out there, but I believe that</p> <p>4 they're flawed.</p> <p>5 Q. You are not aware of any study</p> <p>6 suggesting or concluding that NDMA does not form</p> <p>7 endogenously; true?</p> <p>8 A. I'm not aware of any study that it</p> <p>9 doesn't form endogenously? Is that what you're</p> <p>10 asking? It's a double negative. Can you clarify?</p> <p>11 Q. I'll rephrase it.</p> <p>12 Are there any studies to your</p> <p>13 knowledge that conclude that there is no such</p> <p>14 thing has endogenous formation of NDMA?</p> <p>15 A. No.</p> <p>16 Q. Are you aware of any studies</p> <p>17 suggesting there's no such thing as endogenous</p> <p>18 formation of NDEA?</p> <p>19 A. No.</p> <p>20 Q. You're not going to offer the opinion</p> <p>21 in a courtroom in America suggesting that</p> <p>22 endogenous formation of NDMA or NDEA does not</p> <p>23 occur?</p> <p>24 A. That's correct. I didn't say that.</p> <p>25 I never said that. In fact, what I did say was</p>
Page 186	Page 188
<p>1 are formed endogenously. These are nitrosamines</p> <p>2 such as nitrosoproline that are not metabolized,</p> <p>3 so we can actually track their formation in humans</p> <p>4 by measuring them in urine because they're not</p> <p>5 metabolized.</p> <p>6 But NDMA and NDEA present a different</p> <p>7 problem because they are metabolized, so it's very</p> <p>8 difficult to track their formation in humans.</p> <p>9 So the endogenous formation of NDMA</p> <p>10 and NDEA is very challenging. It's very</p> <p>11 challenging to establish and I don't believe that</p> <p>12 it's been established.</p> <p>13 Q. Well, I agree with you that it's</p> <p>14 challenging. I may agree with you that it's not</p> <p>15 been firmly established, but I think the statement</p> <p>16 you made earlier that's causing me some</p> <p>17 consternation is I believe you said that you do</p> <p>18 not believe and you are of the opinion that there</p> <p>19 is no endogenous formation of NDMA.</p> <p>20 Is that an opinion you intend to</p> <p>21 offer in this case?</p> <p>22 MR. SLATER: Objection.</p> <p>23 You can answer.</p> <p>24 A. No, I don't think I said that or if I</p> <p>25 did say that, it's wrong. What I did say is that</p>	<p>1 that there are studies out there that claim</p> <p>2 endogenous formation of NDMA and NDEA does occur.</p> <p>3 I think it's NDMA mainly. But I believe some of</p> <p>4 the methods in those studies are flawed. That's</p> <p>5 what I said.</p> <p>6 Q. Is it true that the FDA has</p> <p>7 publically stated that the amount of endogenous</p> <p>8 formation of carcinogenic nitrosamines such as</p> <p>9 NDMA and NDEA is unknown?</p> <p>10 A. I believe that's true. I think that</p> <p>11 was one of the conclusions of the workshop.</p> <p>12 Q. Sure. And one of the conclusions of</p> <p>13 the workshop was that no scientist could say</p> <p>14 whether the amount of endogenous formation was</p> <p>15 equal to, less than or greater than our exogenous</p> <p>16 intake of those nitrosamines?</p> <p>17 A. Yes, that's right. We don't know.</p> <p>18 Q. So for all we know, if Gushgari's</p> <p>19 estimates of endogenous intake of a non --</p> <p>20 A. Exogenous. Exogenous.</p> <p>21 Q. Let me start over.</p> <p>22 A. Gushgari estimated exogenous intake.</p> <p>23 Q. Okay. I'm going to try again.</p> <p>24 For all we know, if we use Gushgari's</p> <p>25 estimate of exogenous intake of 2,000 nanograms</p>

<p style="text-align: right;">Page 189</p> <p>1 per day for a non-tobacco user, endogenous NDMA 2 formation could be 2,000 nanograms, could be 3 1,000, could be 3,000 nanograms per day, right? 4 A. Right. We don't know. 5 Q. We don't know. 6 A. Right. 7 Q. Let's just assume that it's -- that 8 endogenous formation and exogenous formation are 9 equal to one another. 10 A. Why would you assume that? 11 Q. I'm going to ask you hypothetically 12 to assume. 13 What that would suggest to us is that 14 any nitrosamine intake for an individual who was 15 taking valsartan-containing medications subject to 16 a recall would be at an even lower percentage than 17 if you had considered simply exogenous intake? 18 MR. SLATER: Objection. 19 A. Yes. Sure. If there's also 20 endogenous formation, then the amount from the 21 drug on a percentage basis obviously would be 22 less. 23 Q. Right. 24 So we used Gushgari's estimates for 25 the mean Mylan exposure and determined it to be</p>	<p style="text-align: right;">Page 191</p> <p>1 be the one I wanted to talk to the Doctor 2 about. 3 Q. About halfway through that -- when's 4 the last time you read this article, sir? 5 A. When was the last time I read it? 6 Q. Yes, sir. 7 A. Probably couple months ago. 8 Q. Fair to say you've read it a couple 9 times since you wrote your report? 10 A. I don't really know. 11 Q. But you certainly would have read it 12 before you wrote your report? 13 A. Yes, I did. 14 Q. While you cited to Gushgari in your 15 report, you did not cite to any problems or 16 limitations or disagreements that you had with his 17 conclusions or analysis, right? 18 A. Oh, yeah. That's true. 19 Q. What Gushgari says here, about 20 halfway through that paragraph that we've 21 highlighted, he says "Recent literature suggests 22 endogenous formation of nitrosamines governs human 23 exposure to these compounds that may account for 24 97% of the total nitrosamine load." 25 Do you see that?</p>
<p style="text-align: right;">Page 190</p> <p>1 0.6% to 7.5%. If we assume endogenous formation, 2 those percentages go down. 3 A. Correct. 4 Q. How much they go down is unknown 5 because, according to you, the scientific 6 community doesn't know how much endogenous 7 formation of nitrosamines takes place? 8 A. I don't think it's just according to 9 me, but yes, that's true. 10 Q. Well, I say that because you're the 11 only person I'm asking today. 12 A. Okay. 13 Q. You've indicated that the level of 14 endogenous formation of nitrosamines is unknown, 15 that there are scientists who have published peer 16 reviewed papers suggesting that endogenous 17 formation is quite high and far exceeds our intake 18 exogenously? 19 A. Yes. 20 Q. One of those people was Gushgari, the 21 guy you cited in your report, right? 22 A. Yes. 23 MR. TRISCHLER: Can you put up page 24 1133 of this paper? Right where you have the 25 cursor, that paragraph right there happens to</p>	<p style="text-align: right;">Page 192</p> <p>1 A. Yes, I see it. 2 Q. So if Gushgari is right, that 3 clean-living individual we've been talking about 4 who takes in 2,000 nanograms per day of 5 nitrosamines endogenously -- or exogenously is 6 getting the other 197,000 endogenously, right? 7 MR. SLATER: Objection. 8 You can answer. 9 A. This is all wrong. I mean, this is 10 crazy because he's talking nitrosamines as a 11 class. So I mean what he's basing this on is 12 nitrosoproline, which is a noncarcinogenic, 13 non-metabolized nitrosamine that's been used as a 14 monitor for endogenous formation. I'm sure that's 15 what that calculation comes from. It had nothing 16 to do with dimethylnitrosamine because 17 nitrosoproline and the other nitros amino acids 18 he's talking about are noncarcinogenic. 19 Q. Where does it say here that he's 20 talking about noncarcinogenic -- 21 A. I don't think it does. I'm sure 22 that's what he's talking about. 23 Q. Did you ask him? 24 A. No, I didn't ask him. 25 Q. How are you sure that's what he's</p>

<p style="text-align: right;">Page 193</p> <p>1 talking about then --</p> <p>2 A. Because I know the literature.</p> <p>3 Q. You have to let me finish the</p> <p>4 question, sir.</p> <p>5 A. You asked me how I knew. I said</p> <p>6 because I know the literature.</p> <p>7 Q. So where did Gushgari ever state that</p> <p>8 his determination that endogenous formation of</p> <p>9 nitrosamines applies only to those noncarcinogenic</p> <p>10 nitrosamines and not nitrosamines thought to be</p> <p>11 carcinogenic?</p> <p>12 A. Thought to be carcinogenic? I don't</p> <p>13 know. I can't speak for Gushgari.</p> <p>14 Q. We talked before about the fact that</p> <p>15 there were 300 plus nitrosamines that have been</p> <p>16 identified in the scientific community.</p> <p>17 How many are carcinogenic?</p> <p>18 A. Most of them. The great majority.</p> <p>19 It's not 300 nitrosamines. It's 300 nitroso</p> <p>20 compounds. Not all nitroso compounds are</p> <p>21 nitrosamines. I think the number for nitrosamines</p> <p>22 is probably closer to 150 to 200.</p> <p>23 Anyhow, that's besides the point.</p> <p>24 What was your question? How many are</p> <p>25 carcinogenic?</p>	<p style="text-align: right;">Page 195</p> <p>1 that are formed endogenously?</p> <p>2 A. No.</p> <p>3 Q. Would you agree that evaluating --</p> <p>4 would you agree that in evaluating the issue of</p> <p>5 whether NDMA or NDEA actually caused cancer in</p> <p>6 humans, we need to consider that nitrosamines form</p> <p>7 both endogenously and exogenously?</p> <p>8 A. Yes.</p> <p>9 Q. And any intake of NDMA or NDEA from</p> <p>10 valsartan-containing medication would be just a</p> <p>11 fraction of an individual's nitrosamine load,</p> <p>12 correct?</p> <p>13 MR. SLATER: Objection.</p> <p>14 A. That's a very poorly phrased</p> <p>15 question, Counselor, I have to say because, again,</p> <p>16 you're mixing carcinogenic nitrosamines --</p> <p>17 highly-carcinogenic nitrosamines, like NDMA and</p> <p>18 NDEA, with noncarcinogenic nitrosamines like</p> <p>19 nitrosoproline.</p> <p>20 So you need to restate the question.</p> <p>21 Q. Well, the question was any intake of</p> <p>22 NDMA or NDEA from valsartan-containing medications</p> <p>23 just a fraction of an individual's daily intake of</p> <p>24 those substances from exogenous and endogenous</p> <p>25 formation?</p>
<p style="text-align: right;">Page 194</p> <p>1 The great majority, but not -- not</p> <p>2 the ones that we have data on for endogenous</p> <p>3 formation. Those are noncarcinogenic.</p> <p>4 Nitrosoproline and some related nitros amino</p> <p>5 acids, that's where all the reliable endogenous</p> <p>6 formation data comes from and those compounds are</p> <p>7 noncarcinogenic because they're not metabolized.</p> <p>8 They're excreted unchanged because they're polar.</p> <p>9 Q. Did you finish your answer?</p> <p>10 A. Yes.</p> <p>11 Q. Endogenous formation of nitrosamines</p> <p>12 can occur with both nitrosamines that are</p> <p>13 carcinogenic and those that are thought to be</p> <p>14 noncarcinogenic, correct?</p> <p>15 A. Yes.</p> <p>16 Q. Have you don't any independent</p> <p>17 scientific research to quantify the levels of</p> <p>18 nitrosamines --</p> <p>19 Strike that.</p> <p>20 Have you done any independent</p> <p>21 scientific research to quantify the levels of NDMA</p> <p>22 that are formed endogenously?</p> <p>23 A. No. We have not done that.</p> <p>24 Q. Have you done any independent</p> <p>25 scientific research to quantify the levels of NDEA</p>	<p style="text-align: right;">Page 196</p> <p>1 MR. SLATER: Objection.</p> <p>2 A. Of total nitrosamines, including the</p> <p>3 noncarcinogenic ones --</p> <p>4 Q. Just those two is my question.</p> <p>5 A. So you're saying -- you start the</p> <p>6 question or sentence -- whatever it was -- with</p> <p>7 NDMA and NDEA and you end the thought -- it's very</p> <p>8 confusing the way you said it. I mean, you have</p> <p>9 to be more specific.</p> <p>10 Q. I was --</p> <p>11 A. What we're talking about here is NDMA</p> <p>12 and NDEA.</p> <p>13 Q. I agree.</p> <p>14 In fairness, you didn't --</p> <p>15 A. The exposure to those is only a</p> <p>16 fraction of the total nitrosamine formation, which</p> <p>17 includes the noncarcinogenic nitrosamines. We</p> <p>18 don't know whether there's NDMA and NDEA formed</p> <p>19 endogenously.</p> <p>20 Q. Well, we do know there --</p> <p>21 A. That's a research question.</p> <p>22 Q. We do know there's NDMA in food?</p> <p>23 A. Yes.</p> <p>24 Q. We do know there's NDMA in beer?</p> <p>25 A. Yes.</p>

<p style="text-align: right;">Page 197</p> <p>1 Q. We do know there's NDMA in air?</p> <p>2 A. I don't know about that. I don't</p> <p>3 think that that's a -- that's a blanket statement.</p> <p>4 It sounds much worse than it is. There's NDMA in</p> <p>5 food, there's NDMA in beer and there's NDMA in</p> <p>6 valsartan. We know that. There's no NDMA --</p> <p>7 extremely small amount -- in water.</p> <p>8 Q. Do you agree that the NDMA observed</p> <p>9 in the valsartan-containing medications is but a</p> <p>10 fraction of the NDMA to which we are exposed to</p> <p>11 exogenously and which we form endogenously?</p> <p>12 MR. SLATER: Objection.</p> <p>13 You can answer.</p> <p>14 A. No, I don't. I agree about the</p> <p>15 exogenous exposure. We already went through that,</p> <p>16 the Gushgari. But I maintain that we don't know</p> <p>17 how much NDMA and NDEAs form endogenously. It</p> <p>18 could very well be zero. So we don't know. We</p> <p>19 don't know the answer to that.</p> <p>20 Q. In the FDA workshop, was this issue</p> <p>21 of relative level of exposure from nitrosamines in</p> <p>22 valsartan-containing medications compared to our</p> <p>23 exposures exogenously and endogenously something</p> <p>24 that was discussed?</p> <p>25 A. Yes, there was quite a bit of</p>	<p style="text-align: right;">Page 199</p> <p>1 MR. TRISCHLER: Please mark as</p> <p>2 Exhibit 14 --</p> <p>3 THE VIDEOGRAPHER: Thirteen.</p> <p>4 MR. TRISCHLER: Thirteen.</p> <p>5 -- the document entitled</p> <p>6 "Nitrosamines as Impurities in Drugs, Health</p> <p>7 Risk Assessment and Mitigation Public</p> <p>8 Workshop," please.</p> <p>9 THE VIDEOGRAPHER: Sure thing.</p> <p>10 (Whereupon, Exhibit 13 was marked for</p> <p>11 identification.)</p> <p>12 MR. SLATER: You're putting up part</p> <p>13 of the transcript here, Clem?</p> <p>14 MR. TRISCHLER: I'm putting up a</p> <p>15 publication from the FDA titled "Nitrosamines</p> <p>16 as Impurities in Drugs, Health Risk</p> <p>17 Assessment and Mitigation Public Workshop."</p> <p>18 Q. Do you see the first page of the</p> <p>19 Exhibit 13, sir?</p> <p>20 A. Yes.</p> <p>21 Q. This was a document that the FDA has</p> <p>22 published from the March 29 and March 30 public</p> <p>23 workshop that you participated in?</p> <p>24 A. Yes.</p> <p>25 Q. Have you read this document before?</p>
<p style="text-align: right;">Page 198</p> <p>1 discussion about endogenous nitrosamine formation.</p> <p>2 Q. And isn't it true in the FDA workshop</p> <p>3 the conclusion that was reached among this panel</p> <p>4 of experts was that the levels of nitrosamines as</p> <p>5 impurities in drugs are likely minuscule in</p> <p>6 comparison to exogenous exposure from foods and</p> <p>7 even more so to endogenous levels?</p> <p>8 MR. SLATER: Objection.</p> <p>9 A. Nitrosamines includes -- first of</p> <p>10 all, I don't think they use the word "minuscule."</p> <p>11 I'm not sure about that. I'd have to check the</p> <p>12 transcript.</p> <p>13 Again, you're mixing apples and</p> <p>14 oranges because, as I said several times already,</p> <p>15 I think, just about everything we know about</p> <p>16 endogenous formation involves noncarcinogenic</p> <p>17 nitrosamines such as nitrosoproline. We don't</p> <p>18 have good data on the endogenous formation of the</p> <p>19 compounds found in valsartan, dimethylnitrosamine.</p> <p>20 MR. TRISCHLER: What's your next</p> <p>21 numbered exhibit?</p> <p>22 THE VIDEOGRAPHER: Our next exhibit</p> <p>23 number will be 13 and Counsel, just to let</p> <p>24 you know, I have about five minutes left on</p> <p>25 the media.</p>	<p style="text-align: right;">Page 200</p> <p>1 A. Yes.</p> <p>2 Q. Do you agree with its content?</p> <p>3 A. Yes.</p> <p>4 MR. SLATER: Objection.</p> <p>5 You can answer.</p> <p>6 Q. Please go to page 14, last paragraph</p> <p>7 of the page.</p> <p>8 About halfway through the page, it is</p> <p>9 written "The levels of nitrosamines as impurities</p> <p>10 in drug are likely minuscule in comparison to</p> <p>11 exogenous exposures from foods and even more so to</p> <p>12 endogenous levels."</p> <p>13 Did I read that correctly?</p> <p>14 A. Yes, you did. But, you know, it's a</p> <p>15 poorly written sentence, but yeah, you read it</p> <p>16 correctly. You're right, it's in the report.</p> <p>17 You're right. I read the report. I wouldn't have</p> <p>18 written it this way.</p> <p>19 Q. It's a poorly written statement that</p> <p>20 you told me you agreed with, right?</p> <p>21 A. Well, first of all, minuscule, I mean</p> <p>22 you said a few minutes ago, I think, from foods it</p> <p>23 was up to 7%. I think you said that. I don't</p> <p>24 know whether that's minuscule. And then even more</p> <p>25 so to endogenous levels.</p>

<p style="text-align: right;">Page 201</p> <p>1 Again, this is really misleading</p> <p>2 because we don't know about the -- the</p> <p>3 nitrosamine -- the endogenous data comes almost</p> <p>4 exclusively from a noncarcinogenic nitrosoproline</p> <p>5 and related nitrosothyoproline and these compounds</p> <p>6 that's that are excreted unchanged and they're</p> <p>7 noncarcinogenic.</p> <p>8 So, I mean, this sentence actually is</p> <p>9 a little misleading. I know it was written by the</p> <p>10 great FDA, but ...</p> <p>11 Q. You were --</p> <p>12 A. I was part of it. Yeah, I reviewed</p> <p>13 it. That's right. You know.</p> <p>14 Q. You were part of the great FDA panel</p> <p>15 when this was --</p> <p>16 A. I was, yeah. I was. Absolutely.</p> <p>17 Q. You have to let me ask a question.</p> <p>18 A. Okay.</p> <p>19 Q. When this was written, did you</p> <p>20 express disagreement with it?</p> <p>21 A. No, I did not.</p> <p>22 Q. Did you tell anyone at FDA that this</p> <p>23 statement was incorrect?</p> <p>24 A. No, I did not.</p> <p>25 Q. So even if we assume for the sake of</p>	<p style="text-align: right;">Page 203</p> <p>1 A. That is correct.</p> <p>2 Q. In your work in this case -- strike</p> <p>3 that.</p> <p>4 When we talk about exogenous intake</p> <p>5 of NDEA and NDMA, we know that can come from</p> <p>6 multiple sources, correct?</p> <p>7 A. Yes.</p> <p>8 Q. In your work in this case, have you</p> <p>9 interviewed any of the individual plaintiffs?</p> <p>10 A. No.</p> <p>11 Q. Have you reviewed any medical records</p> <p>12 from any of the individual plaintiffs?</p> <p>13 A. No.</p> <p>14 Q. Have you reviewed any questionnaires</p> <p>15 completed by any of the individual plaintiffs?</p> <p>16 A. No.</p> <p>17 Q. Have you prepared questionnaires to</p> <p>18 be submitted to any of the individual plaintiffs?</p> <p>19 A. No.</p> <p>20 Q. Have you obtained any information</p> <p>21 from any of the individual plaintiffs regarding</p> <p>22 their dietary habits, smoking history, medical</p> <p>23 history, anything like that?</p> <p>24 A. No.</p> <p>25 Q. Have you reviewed any of the</p>
<p style="text-align: right;">Page 202</p> <p>1 argument that nitrosamines like NDMA and NDEA can</p> <p>2 cause cancer in humans, what we know is that those</p> <p>3 nitrosamines can be formed both endogenously and</p> <p>4 exogenously, correct?</p> <p>5 MR. SLATER: Objection.</p> <p>6 You can answer.</p> <p>7 A. I don't think there's good evidence</p> <p>8 for endogenous formation of NDMA and NDEA.</p> <p>9 Q. I thought you told me before you were</p> <p>10 not going to express the opinion that endogenous</p> <p>11 formation does not occur.</p> <p>12 MR. SLATER: Objection.</p> <p>13 Argumentative.</p> <p>14 A. Double negative.</p> <p>15 MR. SLATER: Is there a question?</p> <p>16 A. Double negative again. I don't know.</p> <p>17 Can you rephrase your question?</p> <p>18 Q. Does endogenous formation of NDEA</p> <p>19 occur?</p> <p>20 A. I don't know.</p> <p>21 Q. Does endogenous formation of NDMA</p> <p>22 occur?</p> <p>23 A. I don't know.</p> <p>24 Q. You can't rule out the possibility</p> <p>25 that endogenous formation of NDEA and NDMA occur?</p>	<p style="text-align: right;">Page 204</p> <p>1 depositions of any of the individual plaintiffs?</p> <p>2 A. No.</p> <p>3 Q. Is there any scientific means to</p> <p>4 measure the quantity of NDEA in the human body?</p> <p>5 A. No. Not accurately.</p> <p>6 Q. I think I asked you about NDEA. For</p> <p>7 completeness, let me ask you about NDMA.</p> <p>8 Is there any scientific means to</p> <p>9 measure the quantity of NDMA in the human body?</p> <p>10 A. Not in my opinion. Not right now,</p> <p>11 no.</p> <p>12 Q. So I take it then that no such</p> <p>13 attempts have been made by you with respect to any</p> <p>14 plaintiff in this case?</p> <p>15 A. No.</p> <p>16 Q. So there's no way to do a blood test,</p> <p>17 a tissue sample or anything like that of an</p> <p>18 individual, look at it and say how much NDMA he or</p> <p>19 she might have in their body at any point in time?</p> <p>20 A. I wouldn't say that. There are ways,</p> <p>21 but I haven't done it. As far as I know, it has</p> <p>22 not been done.</p> <p>23 Q. Maybe I'm confusing myself.</p> <p>24 I thought I had asked you if there</p> <p>25 was any scientific way to measure or quantify NDMA</p>

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<p>1 or NDEA in the body.</p> <p>2 A. There's no established method that's</p> <p>3 accepted as far as I know, but that doesn't mean</p> <p>4 it can't be done.</p> <p>5 Q. How would you hypothetically do it if</p> <p>6 there's no established method for doing it?</p> <p>7 A. I would use mass spectrometry and I</p> <p>8 would use an internal standard that labeled</p> <p>9 internal standard of dimethylamine that would tell</p> <p>10 me whether any artifact formation or any other</p> <p>11 interference was occurring in the method. It can</p> <p>12 be done, but it hasn't been done as far as I know.</p> <p>13 Q. So without some baseline, you don't</p> <p>14 have any data to establish sort of a baseline</p> <p>15 nitrosamine level for any particular plaintiff</p> <p>16 based on their exogenous and endogenous exposures</p> <p>17 to these particular nitrosamines, right?</p> <p>18 A. No. You know, only -- well, what we</p> <p>19 already discussed, I mean, from levels in food and</p> <p>20 that kind of thing. No, not actual measurements.</p> <p>21 Q. So without a baseline --</p> <p>22 A. Like a before and after they took the</p> <p>23 pill or something like that, we don't have that.</p> <p>24 Q. Right.</p> <p>25 So without a per person, individual</p>	<p>1 lunch now? We're way past --</p> <p>2 MR. TRISCHLER: Oh, okay. Sorry</p> <p>3 about that. I lost -- for some reason, my</p> <p>4 clock on my computer is off.</p> <p>5 THE VIDEOGRAPHER: The time is</p> <p>6 2:04 p.m.</p> <p>7 This ends media three.</p> <p>8 (Recess taken)</p> <p>9 THE VIDEOGRAPHER: The time is now</p> <p>10 2:57.</p> <p>11 This begins media four.</p> <p>12 You may proceed.</p> <p>13 (Whereupon, Exhibit 14 was marked for</p> <p>14 identification.)</p> <p>15 Q. Dr. Hecht, are you familiar -- I'm</p> <p>16 not sure if I asked you this question before the</p> <p>17 break. I thought I was ready to introduce a paper</p> <p>18 by Mr. Johnson entitled "Permitted Daily Exposure</p> <p>19 Limits for Noteworthy Nitrosamines." I think that</p> <p>20 would be Exhibit 14.</p> <p>21 Have you seen this paper before?</p> <p>22 Let me know if you need it</p> <p>23 highlighted or blown up.</p> <p>24 A. I don't recognize it.</p> <p>25 MR. TRISCHLER: If you could, just</p>
Page 206	Page 208
<p>1 baseline, there's no -- you don't have any basis</p> <p>2 to opine whether NDMA intake or NDEA intake from</p> <p>3 valsartan-containing medications for any plaintiff</p> <p>4 in this case represented a 1%, 2%, 5% increase in</p> <p>5 their daily exposure to these nitrosamines,</p> <p>6 correct?</p> <p>7 A. No, we don't have that data.</p> <p>8 Q. We don't have that data for either</p> <p>9 NDMA or NDEA?</p> <p>10 A. Correct.</p> <p>11 Q. Are you familiar with --</p> <p>12 A. It would be based on estimates of</p> <p>13 exposure that we know -- we know the amounts in</p> <p>14 food and beer and the things that we discuss, but</p> <p>15 actual measurements we don't have.</p> <p>16 Q. Are you familiar with the Johnson</p> <p>17 paper on permitted daily exposure limits for</p> <p>18 nitrosamines?</p> <p>19 A. Show me the paper.</p> <p>20 MR. TRISCHLER: Sure. I guess it's</p> <p>21 14 I think is what we're up to.</p> <p>22 THE VIDEOGRAPHER: Counsel, just</p> <p>23 we're about seven minutes over.</p> <p>24 Do you mind if we change the media?</p> <p>25 MR. SLATER: Why don't we break for</p>	<p>1 highlight, Bill, the top portion.</p> <p>2 Q. You'll note that the article was</p> <p>3 received in March of this year and accepted for</p> <p>4 publication in May.</p> <p>5 I'm just wondering if you had a</p> <p>6 chance to review this paper or you recall</p> <p>7 reviewing this paper before you wrote your report</p> <p>8 in July of this year?</p> <p>9 A. I haven't seen this.</p> <p>10 Q. In this report, Johnson and his</p> <p>11 colleagues calculate a permitted daily exposure</p> <p>12 level for NDMA and NDEA.</p> <p>13 Have you ever calculated a permitted</p> <p>14 daily exposure limit for any compound?</p> <p>15 A. No.</p> <p>16 Q. Are you familiar with the concept of</p> <p>17 a permitted daily exposure limit?</p> <p>18 MR. SLATER: Objection.</p> <p>19 You can answer.</p> <p>20 A. Yes, in general. But I'm not sure</p> <p>21 about the language.</p> <p>22 Q. Well, it's my understanding that in</p> <p>23 the field of toxicology, a permitted daily</p> <p>24 exposure limit generally refers to a dose that is</p> <p>25 unlikely to cause an adverse effect in an</p>

<p style="text-align: right;">Page 209</p> <p>1 individual is exposed at or below this dose every 2 day of a lifetime. 3 Okay? 4 So accepting that definition, are 5 you -- have you ever attempted to calculate a PDE 6 for any nitrosamine? 7 A. No. 8 Q. If you look at -- I think it's the 9 page 302 of this paper. There's a chart or a 10 table at the top and you'll see that in the last 11 row or last column, Johnson and his colleagues 12 calculated a PDE for NDMA of 6.2 micrograms and a 13 PDE for NDEA of 2.2 micrograms. 14 Do you see that? 15 A. Mm-hmm. Yeah. 16 Q. We talked about the conversions 17 before, but that equates to roughly 18 6,200 nanograms and 2,200 nanograms, right? 19 A. Right. 20 Q. And if you go back to the test data 21 from Mylan that you mentioned in your report, that 22 test data shows an NDEA range for API batches of 23 0.1 parts per million to 1.57 parts per million 24 and I represented to you that the mean 25 concentration was calculated at 0.47.</p>	<p style="text-align: right;">Page 211</p> <p>1 A. Yes. 2 Q. In fact, the mean nanogram 3 concentration would be about 5% of that daily PDE. 4 Correct? 5 A. Right. Yes. 6 Q. Do you have any evidence to suggest 7 to this jury that a plaintiff in this litigation 8 who consumed valsartan-containing medication that 9 came from Mylan ever received a pill that 10 contained nitrosamines above the PDE established 11 by Johnson and his colleagues? 12 A. No, I don't. 13 Q. Earlier in the deposition -- 14 A. No, it's still maintained that none 15 of that should be there. It should be zero. 16 Q. Earlier in the deposition, I had 17 asked you a few questions about how you went about 18 doing your work in this case and you told me that 19 there were, you know, three components of it: 20 One, reviewing publically-available information 21 about the valsartan medications; two, looking at 22 the scientific literature; and three, reviewing 23 documents that came to you from plaintiffs' 24 counsel that related to documents from the 25 manufacturer's defendants.</p>
<p style="text-align: right;">Page 210</p> <p>1 Do you recall that? 2 A. What was the range again? 3 Q. 0.1 parts per million to 1.57 parts 4 per million. That's what you wrote in your 5 report. 6 A. Okay. 7 Q. And I had represented to you that 8 that range resulted in a mean of 0.47. 9 MR. SLATER: Did you say NDMA or NDEA 10 for that range you just gave? 11 MR. TRISCHLER: NDEA, sir. 12 MR. SLATER: Gotcha. 13 A. Okay. 14 Q. Converting that parts per million to 15 a nanogram level based on the 320 milligram dose 16 results in a nanogram concentration of about 17 150 nanograms. 18 Do you recall that math that we did 19 before? 20 A. Yes. 21 Q. So if we use that calculation of 22 150 nanograms of NDEA in a tablet of Mylan's 23 valsartan-containing medication, it's well under 24 the PDE established by Johnson in his 25 peer-reviewed study, correct?</p>	<p style="text-align: right;">Page 212</p> <p>1 Do you generally recall that 2 discussion? 3 A. Mm-hmm. Yes. 4 Q. And you -- we talked about some of 5 the literature that you reviewed earlier, 6 specifically some of the animal studies, correct? 7 A. Yes. 8 Q. In addition to the animal studies, I 9 note in your report, though, that you also discuss 10 a number of dietary studies. I think those are 11 primarily cited at pages 14 and 15 of your report. 12 Is that right? 13 A. Yes. 14 Q. Similar to what we talked about 15 before, was there a particular method that you 16 used to decide what dietary studies you were going 17 to include in this report? 18 A. Well, I looked into literature on 19 epidemiology studies that take into account 20 nitrosamine exposure. 21 Q. Would we be able to go back at this 22 point in time and recreate what literature you 23 would have looked at by means of a -- the results 24 of a literature search or notes or anything that 25 you maintain to tell us what kind of search you</p>

<p style="text-align: right;">Page 213</p> <p>1 did for the literature?</p> <p>2 A. I didn't keep records of the -- of my</p> <p>3 literature search.</p> <p>4 Q. I assume that you would agree with me</p> <p>5 that following a scientific approach to causation</p> <p>6 requires a review of all the relevant literature?</p> <p>7 A. Yes.</p> <p>8 Q. Were there any dietary intake studies</p> <p>9 that you -- addressing the potential</p> <p>10 carcinogenicity of NDMA or NDEA in foods that you</p> <p>11 reviewed beyond the ones that you listed in your</p> <p>12 report?</p> <p>13 A. No, I don't believe so. I think</p> <p>14 they're all listed in the report. It's possible</p> <p>15 that, you know, I may have missed something, but I</p> <p>16 think they're all in the report.</p> <p>17 Q. My apologies. I thought you had</p> <p>18 finished.</p> <p>19 Would you agree with me that there</p> <p>20 have been many observational studies reported in</p> <p>21 the literature where scientists observe no</p> <p>22 statistically significant association between</p> <p>23 nitrosamine intake and food and the cause of</p> <p>24 various cancers?</p> <p>25 A. No. Repeat the question.</p>	<p style="text-align: right;">Page 215</p> <p>1 cancer.</p> <p>2 Agreed?</p> <p>3 A. Sure. But, I mean, there are also</p> <p>4 other studies that do report an association, so I</p> <p>5 think your question should be rephrased.</p> <p>6 Q. That was sort of my point, is that</p> <p>7 there are studies that go both ways. There are</p> <p>8 studies that have been published that report a</p> <p>9 statistically significant association between NDMA</p> <p>10 intake and some foods and the development of</p> <p>11 cancer and there are other studies that have</p> <p>12 reached a contrary result. That's the question I</p> <p>13 was asking.</p> <p>14 A. Mm-hmm. There are both types of</p> <p>15 results -- that's true -- out there.</p> <p>16 Q. In your report --</p> <p>17 A. It's a very challenging study to do.</p> <p>18 Q. Sure.</p> <p>19 In your report, did you attempt to</p> <p>20 list or collect or identify all of those studies</p> <p>21 where no association was found between NDMA in</p> <p>22 food and the onset or development of cancer?</p> <p>23 A. No, I did not.</p> <p>24 Q. What it appears to me that you did --</p> <p>25 and please correct me if I'm wrong -- again, I'm</p>
<p style="text-align: right;">Page 214</p> <p>1 Q. Sure.</p> <p>2 A. What did you say?</p> <p>3 Q. I said have there been observational</p> <p>4 studies reported in the literature where</p> <p>5 scientists observed no statistically significant</p> <p>6 association between nitrosamine intake and food</p> <p>7 and the cause of various cancers?</p> <p>8 A. What do you mean by observational?</p> <p>9 Q. Well, all of these dietary intake</p> <p>10 studies are observational.</p> <p>11 A. Well, sure, broadly speaking, but I'm</p> <p>12 not sure what you mean by observational.</p> <p>13 Q. Let me see if I could ask another</p> <p>14 question.</p> <p>15 A. It's a very broad term.</p> <p>16 Q. I was trying to --</p> <p>17 A. I'm not sure what that means.</p> <p>18 Q. I was just trying to be sort of all</p> <p>19 encompassing with the question. Let me ask it a</p> <p>20 different way then.</p> <p>21 There have been studies that have</p> <p>22 been reported in the literature where scientists</p> <p>23 attempted to evaluate NDMA and NDEA content in</p> <p>24 food and they reported no statistically</p> <p>25 significant association between that intake and</p>	<p style="text-align: right;">Page 216</p> <p>1 looking at pages 14 and 15 of your report -- what</p> <p>2 it appears to me that you did was to discuss the</p> <p>3 studies that you believe reported some association</p> <p>4 between dietary intake of nitrosamines and some</p> <p>5 cancers while ignoring any studies that reached a</p> <p>6 contrary result.</p> <p>7 Is that accurate?</p> <p>8 A. I focused on the ones that showed a</p> <p>9 relationship, yes.</p> <p>10 Q. And you did not discuss the ones that</p> <p>11 don't?</p> <p>12 MR. SLATER: Objection.</p> <p>13 Lack of foundation.</p> <p>14 You can answer.</p> <p>15 A. I don't know. I mean, I may not have</p> <p>16 discussed every study in the literature.</p> <p>17 Q. But what you did do -- and it's on</p> <p>18 page 15, if you want to take a look -- was you</p> <p>19 sort of covered the omission of non-favorable</p> <p>20 studies with one paragraph in which you said</p> <p>21 "Studies do not find a significant association or</p> <p>22 raise questions. This can be explained by smaller</p> <p>23 relatively small sample size, inadequate follow-up</p> <p>24 period to capture all cancers, bias/inadequate</p> <p>25 dose quantification, potentially mitigating</p>

<p style="text-align: right;">Page 217</p> <p>1 dietary factors such as vitamin C intake and 2 others." 3 Right? 4 A. Right. 5 Q. So what it sounds to me like what 6 you're suggesting is that you're acknowledging 7 that the dietary intake studies evaluating the 8 role of nitrosamines in diet and the onset of 9 cancer have gone both ways, right? 10 A. Yes. 11 Q. And what it sounds like what you did 12 in your report is simply to say that in the 13 studies that find no association, you discredit 14 those by saying that they're subject to either 15 poor study design or confounding factors? 16 MR. SLATER: Objection. 17 You can answer. 18 A. Well, you know, just about all of 19 these studies can be criticized for one reason for 20 another. I mean, these types of studies are 21 extremely difficult to do, so they can be 22 criticized, but yeah, I didn't cover all of the -- 23 I didn't attempt to cover all of the studies of 24 diet and nitrosamine content in foods and cancer. 25 I did not attempt to do that.</p>	<p style="text-align: right;">Page 219</p> <p>1 (Whereupon, Exhibit 15 was marked for 2 identification.) 3 Q. Are you familiar with this work, sir? 4 A. Yes, I am. 5 Q. What the authors of this study found 6 was that there was an association between lung 7 cancer and a diet that was rich in fats, correct? 8 A. Yes. 9 Q. They never excluded and they could 10 not exclude was any association was due to dairy 11 products, desserts or other fatty foods, correct? 12 A. I don't know about dairy products. 13 I'd have to look at it more closely. 14 Q. You could look at the -- 15 A. I'd have to read it. 16 Q. I can have our technician -- 17 A. I mean do they -- I think they 18 describe the questionnaire in there, so I have to 19 look at that more carefully. 20 MR. TRISCHLER: Bill, can you 21 highlight the top portion, please? 22 THE WITNESS: Yes. 23 Q. So what the paper says in that last 24 sentence that was highlighted there is that what 25 the data from the Goodman study indicates is that</p>
<p style="text-align: right;">Page 218</p> <p>1 Q. And I understand -- 2 A. But I did give examples of where 3 nitrosamine contamination in food has been linked 4 to cancer and there are a number of them. 5 Q. Right. I understand that there are 6 difficulties in doing these studies and that they 7 all have their limits, but when I read your 8 report, what it suggests is that the only studies 9 that you criticized as being limited by 10 confounding factors are the ones that found no 11 association between cancer and NDMA intake? 12 A. That's not necessarily true. 13 Q. Isn't that what that paragraph in 14 page 15 means when we read it? 15 A. I don't know. You know, I mean, this 16 criticism can also apply to some of the positive 17 sides. It's a general criticism. 18 Q. Well, let's take a look at some of 19 the studies that you do cite to, if we can. 20 Okay? 21 A. Okay. 22 MR. TRISCHLER: You cite to a study 23 by Goodman, G-O-O-D-M-A-N, entitled "High Fat 24 Foods and the Risk of Lung Cancer." 25 Can we mark that as Exhibit 15?</p>	<p style="text-align: right;">Page 220</p> <p>1 smokers with a high intake of foods rich in fat 2 and animal protein and who have a preference for 3 cured meats are at increased risk of lung cancer. 4 A. That's what they concluded. 5 Q. That's not really a surprising or 6 controversial finding, is it? 7 A. No. A study like this would be very 8 difficult to do in smokers. I could be critical 9 of this study for that reason, but this is what 10 they found and it's a good group. It's a very 11 highly respected group. 12 Q. When we talk about confounding, any 13 attempt to link these results to NDMA consumption 14 would be limited by confounding factors relating 15 to dietary intake of other fatty foods such as 16 dairy products and desserts, right? That would be 17 one confounding factor? 18 A. The main confounding factor would be 19 smoking. That would blow away other confounding 20 factors. But they found a risk in addition to 21 smoking from cured meats and foods rich in fat and 22 animal protein. It's a very difficult study to 23 do. Very challenging because of the overwhelming 24 effect of smoking. 25 Q. While smoking might be the primary</p>

<p style="text-align: right;">Page 221</p> <p>1 confounding factor, there are others, correct?</p> <p>2 A. Yes.</p> <p>3 Q. By the way, the control group in this</p> <p>4 Goodman study was, I think, 326 subjects.</p> <p>5 Was that a significant and adequate</p> <p>6 test sample size in your judgment?</p> <p>7 A. That's relatively small by current</p> <p>8 standards. This was published in 1992, I believe.</p> <p>9 That's a relatively small sample size.</p> <p>10 Q. Sorry.</p> <p>11 Do you agree that a good scientist</p> <p>12 would not draw conclusions or inferences from a</p> <p>13 study that even the authors of that study would</p> <p>14 not support?</p> <p>15 MR. SLATER: Objection.</p> <p>16 We went through this earlier.</p> <p>17 A. I'm not sure what that question even</p> <p>18 means. Why wouldn't the authors support their own</p> <p>19 study? I don't understand that.</p> <p>20 Q. I said they would not support.</p> <p>21 Can you as a scientist reach</p> <p>22 conclusions that the authors themselves do not</p> <p>23 draw?</p> <p>24 MR. SLATER: Objection.</p> <p>25 You went over this earlier, Counsel.</p>	<p style="text-align: right;">Page 223</p> <p>1 and I'll refer Counsel to the Eighth Circuit</p> <p>2 decision that came out yesterday that</p> <p>3 addressed this exact question and he knows</p> <p>4 it, I'm sure, and asked these questions</p> <p>5 earlier in the deposition. I don't</p> <p>6 appreciate that.</p> <p>7 We'll take it into account if and</p> <p>8 when defense counsel asks for more than seven</p> <p>9 hours on the record with this witness.</p> <p>10 You can answer.</p> <p>11 A. There may be different</p> <p>12 interpretations of data. It for sure can happen.</p> <p>13 Q. Do you agree that --</p> <p>14 A. The authors of a paper may interpret</p> <p>15 their data in a certain way and, you know, then</p> <p>16 it's reviewed and the reviewers may agree with it,</p> <p>17 the editors of the journal may agree with it, but</p> <p>18 other scientists may not agree with the</p> <p>19 interpretation.</p> <p>20 Q. Do you agree that a scientist should</p> <p>21 not cherry-pick data from a study that might</p> <p>22 support his or her hypothesis while ignoring other</p> <p>23 parts of the study that call the conclusion into</p> <p>24 question?</p> <p>25 A. Yes.</p>
<p style="text-align: right;">Page 222</p> <p>1 I thought we're not going to</p> <p>2 duplicate areas of questioning in light of</p> <p>3 the time issue.</p> <p>4 A. For this study or any study?</p> <p>5 Q. For any study.</p> <p>6 MR. SLATER: I object.</p> <p>7 Counsel, you do realize you went over</p> <p>8 this entire line of questioning earlier in</p> <p>9 the deposition, right? You're just going to</p> <p>10 ignore me, I guess? Okay. Well, I don't</p> <p>11 appreciate that you're going to go through a</p> <p>12 line of questioning you already did hours ago</p> <p>13 or are you representing you didn't ask this</p> <p>14 question already and go down this line</p> <p>15 already?</p> <p>16 MR. TRISCHLER: I've got a question</p> <p>17 pending. I'm just waiting on an answer,</p> <p>18 Adam.</p> <p>19 MR. SLATER: You're ignoring me?</p> <p>20 Thank you.</p> <p>21 A. What was the question again?</p> <p>22 Q. Is it good practice for a scientist</p> <p>23 to draw conclusions from a paper that the authors</p> <p>24 of that paper do not support?</p> <p>25 MR. SLATER: Again, I object to this</p>	<p style="text-align: right;">Page 224</p> <p>1 Q. You also cite to a paper that was</p> <p>2 written by a gentleman named Paul Knekt,</p> <p>3 K-N-E-K-T. I'm sure I'm mispronouncing that.</p> <p>4 But are you familiar with the paper?</p> <p>5 A. Yes.</p> <p>6 MR. TRISCHLER: We'll mark that as</p> <p>7 Exhibit 16, I think.</p> <p>8 (Whereupon, Exhibit 16 was marked for</p> <p>9 identification.)</p> <p>10 Q. You cited to the Knekt paper in your</p> <p>11 report in this case, correct?</p> <p>12 A. Yes.</p> <p>13 Q. Do you recall reading this study</p> <p>14 and --</p> <p>15 A. Yes, I read it. Absolutely. I did</p> <p>16 absolutely read it.</p> <p>17 Q. One of the first things that I note</p> <p>18 right off the bat when I read this study is in the</p> <p>19 very first sentence at the top, the authors note</p> <p>20 that the relationship of dietary nitrosamines to</p> <p>21 human cancer is uncertain.</p> <p>22 Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. We talked about how some studies are</p> <p>25 difficult, some are flawed, some are well</p>

<p style="text-align: right;">Page 225</p> <p>1 designed, some are not.</p> <p>2 Was this Knekt study one that you</p> <p>3 considered to be a good, well-designed study?</p> <p>4 A. Show me the -- show me the -- you</p> <p>5 have to show me more.</p> <p>6 Q. Which part --</p> <p>7 A. I want to make sure -- hold on a</p> <p>8 second.</p> <p>9 Q. Sure.</p> <p>10 A. Let me just look at my own notes.</p> <p>11 Yes. Okay. Yes, go ahead. What was your</p> <p>12 question.</p> <p>13 Q. I think I asked you whether in your</p> <p>14 judgment this was a good, well-designed study.</p> <p>15 A. Yes, it was.</p> <p>16 Q. Can we rely on its conclusions then?</p> <p>17 A. Yes.</p> <p>18 MR. SLATER: Objection.</p> <p>19 Q. In this study by Knekt, the authors</p> <p>20 observed that there was no increased risk of</p> <p>21 cancer from NDMA for any cancers of the GI tract.</p> <p>22 Correct?</p> <p>23 A. They found an increased risk of</p> <p>24 colorectal cancer among individuals with a high</p> <p>25 intake of NDMA. That's what it says.</p>	<p style="text-align: right;">Page 227</p> <p>1 A. Correct.</p> <p>2 Q. They observed no increased risk of</p> <p>3 esophageal cancer, correct?</p> <p>4 A. Correct.</p> <p>5 Q. While as you point out in this Knekt</p> <p>6 study the authors did find an association between</p> <p>7 NDMA and colorectal cancer, even those authors</p> <p>8 observed that this observation might be due to</p> <p>9 confounding, correct?</p> <p>10 A. It's possible.</p> <p>11 Q. It's not possible. It's what they</p> <p>12 said.</p> <p>13 A. Yes, I'm agreeing with you. It's</p> <p>14 possible that it could be due to confounding.</p> <p>15 That's always an issue in epidemiology studies.</p> <p>16 Q. When we talk about dietary studies</p> <p>17 like this and others that you cited and reviewed,</p> <p>18 they're all based on self-reported dietary</p> <p>19 behavior, correct?</p> <p>20 A. No. Yes. Yes, they are. Yes and</p> <p>21 no. Okay? So I mean in some of these studies --</p> <p>22 so they, you know, the subjects fill out</p> <p>23 questionnaires about diet. That's self-reporting.</p> <p>24 But the investigators used data -- very extensive</p> <p>25 data -- on dimethyl and dimethylnitrosamine in</p>
<p style="text-align: right;">Page 226</p> <p>1 Q. Right. I didn't ask you about that,</p> <p>2 though. My question was --</p> <p>3 A. What did you ask me then?</p> <p>4 Q. My question was --</p> <p>5 A. The GI tract --</p> <p>6 Q. -- the authors observed there was no</p> <p>7 increased risk of NDMA for any cancers of the GI</p> <p>8 tract.</p> <p>9 Is that true or not?</p> <p>10 A. You know --</p> <p>11 Q. I guess I should say any other</p> <p>12 cancers of the GI tract.</p> <p>13 A. Yes, that's true. They observed for</p> <p>14 colorectal. Colorectal.</p> <p>15 Q. They observed no increase --</p> <p>16 A. In the first sentence of the</p> <p>17 discussion --</p> <p>18 Q. They did --</p> <p>19 A. -- "We found an increased risk of</p> <p>20 colorectal cancer among individuals with a high</p> <p>21 intake of NDMA and of colorectal" -- it's part of</p> <p>22 the GI tract, I think.</p> <p>23 Q. Thank you.</p> <p>24 They observed no increased risk of</p> <p>25 stomach cancer, correct?</p>	<p style="text-align: right;">Page 228</p> <p>1 food in order to make the calculations. So it's</p> <p>2 not like somebody self-reports, you know, I don't</p> <p>3 think I was exposed to much dimethylnitrosamine</p> <p>4 yesterday or anything like that. It's the</p> <p>5 self-reporting for the kinds of foods that they --</p> <p>6 which is pretty reliable.</p> <p>7 So they ask the subjects -- you know,</p> <p>8 they could give them a big table of different</p> <p>9 types of food and methods of preparation,</p> <p>10 everything, and the subjects fill out these</p> <p>11 questionnaires so that the investigators know</p> <p>12 basically what the person's diet consisted of.</p> <p>13 Then they use that information and</p> <p>14 tables which are developed by the government</p> <p>15 agencies in that country -- for example, in</p> <p>16 Europe, by the EU -- tables that give the</p> <p>17 nitrosamine content of many different types of</p> <p>18 food in great accuracy and they combine this</p> <p>19 information with the personal dietary information.</p> <p>20 It's not like they're asking people "Did you</p> <p>21 consume any nitrosamines today?" The people</p> <p>22 answering the questions have no idea. They're</p> <p>23 just -- they're just explaining what their</p> <p>24 customary diet is, which people can do with great</p> <p>25 accuracy. This is particularly true in cohort</p>

<p style="text-align: right;">Page 229</p> <p>1 studies where you're interviewing healthy people 2 and then following them for years. 3 Q. Have you finished your answer? 4 A. Yes. 5 Q. Have you seen any of the 6 questionnaires that were used in the Knekt study 7 that were talked about right now? 8 A. No, I didn't see the actual 9 questionnaires. 10 Q. Have you seen any of the -- 11 A. I did not. 12 Q. Have you seen any of the 13 questionnaires in any of the studies that you cite 14 in your paper? 15 A. No, I haven't seen the actual 16 questionnaires, but I'm familiar with -- I'm 17 familiar with epidemiologists, I'm familiar with 18 the general topic of diet and cancer from my 19 previous experience in cancer research and from 20 having served on study sections and having been 21 involved in evaluations of areas -- lifestyle 22 habits and cancer, etc., etc. 23 So I've been in a lot of -- I've been 24 on many different committees that have evaluated 25 this kind of work. I've worked with</p>	<p style="text-align: right;">Page 231</p> <p>1 A. No. 2 Q. Did you see the tables used in any of 3 the studies that you cite to calculate nitrosamine 4 or to estimate nitrosamine exposures? 5 A. I did not see the actual raw data 6 tables, no. I depended on the published studies. 7 The published information. 8 Q. In all of these -- 9 A. But I'm familiar with the kinds of 10 tables that they're using. I am a consultant for 11 the FSA. That's the European Food Safety 12 Authority. I'm familiar with the kinds of data 13 they have and that's the kind of data that was 14 used in these studies. 15 Q. Are you finished? 16 In any of the studies that you cite, 17 is the actual NDMA content in the foods consumed 18 by the subjects ever measured? 19 A. Not in the specific foods, but in the 20 categories of foods, yes. Definitely. 21 Q. Measured by whom? 22 A. I can't give you an answer to that 23 question, but going back to what I said before, 24 FSA and others have consulting laboratories that 25 make these measurements using well-established and</p>
<p style="text-align: right;">Page 230</p> <p>1 epidemiologists, so I'm familiar with diet and 2 cancer studies and the approaches that are used, 3 but I didn't see the -- I didn't see the 4 particular diet questionnaire that was used for 5 this study or for any of the other studies for 6 that matter. 7 MR. TRISCHLER: Object and move to 8 strike as non-responsive. 9 Q. Did you see any of the tables that 10 were used to estimate NDMA exposures in the Knekt 11 study? 12 A. I didn't see the tables themselves, 13 but I'm familiar with this kind of table. 14 Q. I didn't ask if you were familiar -- 15 A. All right. 16 Q. I said did you -- 17 A. You asked me the question. Okay? 18 Q. Right -- 19 A. So I'm telling you I'm familiar with 20 the studies that are done, the kind of tables. 21 All right? 22 Q. I appreciate that, but I'm entitled 23 to answers to the questions I ask. 24 Did you see the tables that were 25 used --</p>	<p style="text-align: right;">Page 232</p> <p>1 well-developed methods. 2 Q. You said you worked with FSA and are 3 working with them right now, correct? 4 A. Yes, that's right. 5 Q. Have you seen FSA publications 6 estimating NDMA content in various foods? 7 A. We're working on it. 8 Q. You're working on it? Have you 9 seen -- 10 A. I've seen the data. Yes, I've seen 11 the data. 12 Q. Have they ever published any of it? 13 A. Not yet, no. 14 Q. Okay. 15 So if FSA hasn't published any of its 16 data, none of the authors of any of these papers 17 would have ever used it, correct? 18 A. No, no, no. They published data 19 before. I'm talking about this particular report. 20 There's plenty of published data on nitrosamine 21 levels in food and plenty of unpublished data also 22 by government regulatory authorities. 23 Q. I'm asking you about FSA because you 24 brought them up. 25 A. Yeah. I'm telling you what they're</p>

<p style="text-align: right;">Page 233</p> <p>1 doing now.</p> <p>2 Q. Try to let me ask the question,</p> <p>3 please.</p> <p>4 A. I'm not sure exactly what they were</p> <p>5 doing at the time of some of these other studies,</p> <p>6 but there's plenty of -- there's plenty of data</p> <p>7 out there, reliable data on nitrosamine content in</p> <p>8 various foods.</p> <p>9 MR. TRISCHLER: Object and move to</p> <p>10 strike as non-responsive.</p> <p>11 Q. Sir, has FSA ever published any data</p> <p>12 on nitrosamine -- on nitrosamine levels in foods?</p> <p>13 A. I believe they have.</p> <p>14 Q. Have you ever seen it?</p> <p>15 A. Maybe.</p> <p>16 Q. Do you have it?</p> <p>17 A. I don't have it in my hands. I'd</p> <p>18 have to look -- FSA has the so-called FSA Journal</p> <p>19 where they publish a very detailed compendium and</p> <p>20 it's very likely that there's something in there</p> <p>21 on nitrosamines in food, but I can't cite it</p> <p>22 offhand.</p> <p>23 Q. One of the things that --</p> <p>24 A. You know, you can look. Look in the</p> <p>25 FSA Journal.</p>	<p style="text-align: right;">Page 235</p> <p>1 some notes and you pulled out, I'm guessing, some</p> <p>2 notes. It appears you're looking at something.</p> <p>3 What are you looking at now?</p> <p>4 A. I'm looking at the Loh paper.</p> <p>5 Q. Before you mentioned that you had</p> <p>6 some notes when I think I was asking you about the</p> <p>7 Knekt paper we had out before.</p> <p>8 Do you have notes that you took from</p> <p>9 your review of these studies?</p> <p>10 A. What do you mean, notes? I read the</p> <p>11 papers and, you know, I underlined and circled</p> <p>12 certain passages.</p> <p>13 Q. Did you write any notes based on --</p> <p>14 A. No, I didn't write any notes. No.</p> <p>15 Q. So what you have in front of you then</p> <p>16 is just a binder of studies?</p> <p>17 A. Yes.</p> <p>18 Q. Are there any studies -- thank you.</p> <p>19 Are there any studies in the binder</p> <p>20 that are not cited in your report?</p> <p>21 A. No. All of these come from my</p> <p>22 report.</p> <p>23 Q. And the only markings that you made</p> <p>24 in your review then are highlighting and circling</p> <p>25 or underlining those types of things?</p>
<p style="text-align: right;">Page 234</p> <p>1 Q. One of the things that you and I</p> <p>2 talked about a few minutes ago was that the</p> <p>3 dietary studies have been inconsistent in terms of</p> <p>4 knowing an association between dietary intake of</p> <p>5 nitrosamines and cancer, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And just by way of one example, you</p> <p>8 cited to a paper that was published by an author</p> <p>9 named Loh, L-O-H.</p> <p>10 Do you recall that paper?</p> <p>11 A. Yes.</p> <p>12 MR. TRISCHLER: One thing I wanted to</p> <p>13 ask you about is if you -- we'll mark that as</p> <p>14 Exhibit 16, I think, and 17 maybe.</p> <p>15 THE VIDEOGRAPHER: We're on 17.</p> <p>16 (Whereupon, Exhibit 17 was marked for</p> <p>17 identification.)</p> <p>18 MR. TRISCHLER: If you go to 1057 of</p> <p>19 that document, please, the first paragraph of</p> <p>20 text below the table, can you highlight that</p> <p>21 for the benefit of the witness?</p> <p>22 Q. Are you able to see what is on the</p> <p>23 screen, sir?</p> <p>24 A. Yes.</p> <p>25 Q. I see that you referred earlier to</p>	<p style="text-align: right;">Page 236</p> <p>1 MR. SLATER: Objection.</p> <p>2 That wasn't the testimony.</p> <p>3 You can answer.</p> <p>4 A. What's your question?</p> <p>5 Q. I'm trying to understand when you</p> <p>6 made reference before that you wanted to "pull</p> <p>7 your notes," I'm trying to understand what you</p> <p>8 meant by notes.</p> <p>9 A. Yes. The binder. I read the papers</p> <p>10 in the binder and as I read them, I circled or</p> <p>11 underlined certain statements that I thought might</p> <p>12 be relevant.</p> <p>13 Q. Did you write any text --</p> <p>14 A. No.</p> <p>15 Q. -- in those notes?</p> <p>16 A. No, I did not.</p> <p>17 Q. So if we -- what we're looking at now</p> <p>18 on Exhibit 17 is a part of the Loh paper. It</p> <p>19 looks like you have the actual paper in your</p> <p>20 notebook, correct, or binder?</p> <p>21 A. This is American Journal of Clinical</p> <p>22 Nutrition.</p> <p>23 Is that the one you're talking about?</p> <p>24 Q. Yes, sir.</p> <p>25 A. 2011?</p>

<p style="text-align: right;">Page 237</p> <p>1 Q. Yes.</p> <p>2 A. Yes.</p> <p>3 Q. What we were talking about before,</p> <p>4 again, is how the studies have been inconsistent</p> <p>5 and that's one of the things that Dr. Loh observes</p> <p>6 in this paper, correct?</p> <p>7 A. Yes.</p> <p>8 Q. Basically, as we look at -- as we're</p> <p>9 looking at right here, what Loh observed was that</p> <p>10 there'd been published studies with respect to</p> <p>11 gastric cancer that go both ways. Some report a</p> <p>12 positive association with gastric cancer, while</p> <p>13 others do not, right?</p> <p>14 A. Insufficient evidence for esophageal</p> <p>15 cancer, but a positive association between</p> <p>16 nitrosamine intake and gastric cancer. So I think</p> <p>17 you said -- I don't think that's what you said.</p> <p>18 You said a positive association</p> <p>19 between nitrite and nitrosamine intake and gastric</p> <p>20 cancer. That's what Loh is saying. Not what you</p> <p>21 said. Insufficient evidence for esophageal</p> <p>22 cancer. I think you said --</p> <p>23 Q. I'm looking at --</p> <p>24 A. -- both positive and negative --</p> <p>25 Q. I'm looking at the sentence that says</p>	<p style="text-align: right;">Page 239</p> <p>1 You went a little quick again. Just</p> <p>2 give me a second to object.</p> <p>3 I object to the foundation of that</p> <p>4 question.</p> <p>5 Q. And Loh's work did not support and</p> <p>6 cannot be cited for support for a statistical</p> <p>7 association between NDMA and esophageal cancer,</p> <p>8 correct?</p> <p>9 A. Correct.</p> <p>10 Q. Not only are the dietary study</p> <p>11 results conflicting, but the authors of those</p> <p>12 studies have even acknowledged that they're not</p> <p>13 reliable in attempting to establish causation of</p> <p>14 cancer, correct?</p> <p>15 A. Where is that?</p> <p>16 Q. I'm asking. I'm not saying it's in</p> <p>17 this paper. I'm just asking --</p> <p>18 A. I haven't seen that they said it's</p> <p>19 not reliable. Maybe you know where that is, but I</p> <p>20 haven't seen it. Where the authors of the study</p> <p>21 said their study was not reliable? I haven't seen</p> <p>22 that. If they didn't think it was reliable, they</p> <p>23 wouldn't try to publish it.</p> <p>24 Q. The question that I was asking was a</p> <p>25 little bit broader than that. I was simply asking</p>
<p style="text-align: right;">Page 238</p> <p>1 in his review -- "In this review, cohort studies</p> <p>2 reported no association for nitrite and NDMA</p> <p>3 intakes with gastric cancer risk."</p> <p>4 Do you see that?</p> <p>5 A. Cohort studies. Right. Cohort</p> <p>6 studies.</p> <p>7 Q. Right. That's what I'm saying.</p> <p>8 The studies on gastric cancer and</p> <p>9 NDMA have gone both ways. Some have said there's</p> <p>10 an association, others have found to the contrary.</p> <p>11 A. Correct. Correct. You're right.</p> <p>12 Q. Loh is simply reporting that,</p> <p>13 correct?</p> <p>14 A. Yes.</p> <p>15 Q. In Loh's own study, it goes on to</p> <p>16 note that they did not find a statistically</p> <p>17 significant association between NDMA and colon</p> <p>18 cancer, right?</p> <p>19 A. I think they found association with</p> <p>20 rectal cancer, but not colon cancer.</p> <p>21 Q. Correct.</p> <p>22 They found no association with</p> <p>23 gastric cancer?</p> <p>24 A. Correct.</p> <p>25 MR. SLATER: Objection.</p>	<p style="text-align: right;">Page 240</p> <p>1 you if you would agree with me that given the</p> <p>2 inconsistencies that have been observed in the</p> <p>3 findings in these dietary studies that one cannot</p> <p>4 rely on those studies to suggest a causal</p> <p>5 connection between NDMA intake and cancer.</p> <p>6 A. No, I do not agree whatsoever.</p> <p>7 Q. Are you familiar with --</p> <p>8 A. There's plenty of evidence from these</p> <p>9 studies. It's not totally consistent in the sense</p> <p>10 that different tissues are implicated in different</p> <p>11 studies, but there's -- overall there are a number</p> <p>12 of -- particularly, the cohort studies,</p> <p>13 particularly those that have information on</p> <p>14 exposure that do indicate a connection between</p> <p>15 dietary nitrosamines and cancer. I don't agree</p> <p>16 with you.</p> <p>17 Q. Okay.</p> <p>18 Here, we're looking at an analysis of</p> <p>19 cohort studies by an author of a paper that you</p> <p>20 cited that says there's no association with NDMA</p> <p>21 and gastric cancer.</p> <p>22 A. Gastric cancer.</p> <p>23 Q. And you agree with that?</p> <p>24 A. What I said was that there are cohort</p> <p>25 studies that show an association between NDMA and</p>

<p style="text-align: right;">Page 241</p> <p>1 cancer, GI cancer. Not necessarily gastric 2 cancer. GI tract, colon, rectum -- 3 Q. Are you familiar with the -- 4 A. -- and others. 5 Q. -- song, S-O-N-G, paper? 6 A. Yes. 7 Q. It's entitled "Dietary Nitrates, 8 Nitrites and Nitrosamine Intake and the Risk of 9 Gastric Cancer, a Meta Analysis"? 10 A. Yes. 11 Q. What's a meta analysis? 12 A. Meta analysis, they combine data from 13 multiple different studies and combine them into 14 one statistical package that they use to do the 15 analysis. So it enables you to have a much larger 16 number of subjects than you would in a single 17 study. 18 Q. So Song pulled data from a lot of 19 different studies? 20 A. Yes. 21 Q. Isn't it true -- 22 A. Eleven studies. 23 Q. Okay. 24 Isn't it true that they -- that the 25 authors of the Song paper concluded that they</p>	<p style="text-align: right;">Page 243</p> <p>1 identification.) 2 THE VIDEOGRAPHER: This is Exhibit 3 18. 4 Do you want me to jump to 9893? 5 MR. TRISCHLER: He seems to be 6 reading it. If he wants you to, you can. 7 We'll let him read it -- 8 A. It's right in the abstract. The 9 summary relative risk of stomach cancer was 1.34 10 for NDMA. It's in the abstract. 11 Q. So you read the abstract? 12 A. I read the whole paper. 13 Q. I'm sorry? 14 A. Huh? 15 Q. I said you read the abstract, 16 correct? 17 A. I read the whole paper. 18 Q. All right. 19 Did you read the conclusion that 20 appears on page 9893? 21 A. Dietary nitrates intake was 22 associated with a reduced risk of gastric cancer 23 and high consumption of nitrites and NDMA could 24 increase the risk. They go on to say that they 25 could not absolutely confirm the reliability of</p>
<p style="text-align: right;">Page 242</p> <p>1 could not confirm the reliability of any 2 conclusions with respect to an association between 3 NDMA and cancer? 4 A. I have to look at it. I have to look 5 at it. 6 Q. It's up on the screen. We could go 7 to page 9893, if you'd like. 8 MR. SLATER: Hang on, Counsel. 9 Of course if Dr. Hecht wants to look 10 through the study before you continue, he's 11 allowed to, right? 12 MR. TRISCHLER: Of course. I was 13 just -- 14 MR. SLATER: I think that's what he 15 was doing. 16 MR. TRISCHLER: He could look if he 17 wants. He could read the whole thing if he'd 18 like. 19 MR. SLATER: Okay. 20 THE VIDEOGRAPHER: Counsel, sorry to 21 cut in. You didn't announce you were going 22 to mark this. Would you like this marked as 23 the next one? 24 MR. TRISCHLER: Sure. 25 (Whereupon, Exhibit 18 was marked for</p>	<p style="text-align: right;">Page 244</p> <p>1 the findings, which of course is applicable to 2 many epidemiologists, particularly diet and 3 cancer. 4 Q. Can we agree even though those 5 instances where a study notes or observes an 6 association that that association does not 7 establish causation? 8 MR. SLATER: Objection. 9 You can answer. 10 A. That depends on the study. I think 11 if we look at things like smoking and cancer and 12 UV and cancer where, you know, the relative risks 13 are extremely high, then you say yes, causation. 14 And, you know, you have to take into account all 15 of the data. So if we have a situation where 16 there's exposure to a carcinogen, which has 17 well-known carcinogenic effects on very low doses, 18 such as NDMA, and can be considered, it should be 19 regarded for practical purposes as if it were a 20 carcinogen to humans, then yes, that equals 21 causation. 22 Q. Let me be more specific. 23 Have you seen any paper published in 24 the literature that suggests that the -- that 25 there's a causal connection between exogenous NDMA</p>

<p style="text-align: right;">Page 245</p> <p>1 intake and the -- and the cause of cancer in 2 humans? 3 A. Yes. We just discussed -- what we've 4 been talking about the last hour. 5 Q. Show me where it says that these 6 exogenous NDMA intake in diet cause cancer. Where 7 does it say that, sir? 8 A. Causes cancer? 9 Q. Yes, that was the question. 10 A. No. The language is much more 11 cautious, of course. It has to be. 12 Q. I'm asking you has there ever been a 13 paper published where it's been concluded that 14 NDMA -- exogenous NDMA intake in food caused 15 cancer? 16 A. I would say collectively the papers 17 that we reviewed indicate that NDMA in food does 18 cause cancer. Otherwise, they wouldn't have seen 19 these elevated relative risks in all of these 20 different studies, some of which were very large. 21 Q. Show me a -- find me a statement in 22 any of the papers in your notebook where that 23 conclusion was made by an author of a published 24 study? 25 A. There isn't. That cause cancer?</p>	<p style="text-align: right;">Page 247</p> <p>1 the literature. 2 Q. Did you suggest to me and to this 3 jury a little bit ago that the mere association 4 between NDMA and cancer is enough to establish 5 causation? Is that what you want us to believe? 6 A. I'm saying that there are a number of 7 strong studies where we have good solid dose 8 information and we have good solid information on 9 cancers that occurred and the study design is 10 strong, such that collectively they present a 11 conclusion that NDMA can cause cancer. Whether it 12 does cause cancer, I would say it still needs 13 research. 14 Q. By the -- 15 A. I go back to this again. 16 Q. By the same token -- 17 MR. SLATER: For the record, that was 18 referring to the 1978 IARC publication? 19 THE WITNESS: Yes. 20 Q. By the same token, those same studies 21 in the literature include many studies where there 22 have been no association observed between NDMA and 23 cancer, correct? 24 A. I don't know about many. There are 25 some.</p>
<p style="text-align: right;">Page 246</p> <p>1 Q. Right. It's not -- 2 A. It did not say that. 3 Q. It's never been written in the 4 scientific literature that dietary intake of NDMA 5 has caused cancer; true? 6 A. In humans. 7 Q. In humans. Correct. 8 A. Caused cancer, correct. 9 Q. Never been -- 10 A. You can't -- 11 Q. Never been written -- 12 A. There's still not enough data to say 13 absolutely cause cancer. 14 Q. You've got to let me ask a question, 15 sir. 16 It's never been written anywhere in 17 the scientific literature that dietary exposure to 18 NDEA has caused cancer in humans, has it? 19 A. Now you're on NDEA? 20 Q. Yes. 21 A. Okay. I thought you were talking 22 about NDMA. 23 I do not believe that there is such a 24 study, yes, where it says NDEA caused cancer in 25 humans. I don't think there is such a study in</p>	<p style="text-align: right;">Page 248</p> <p>1 Q. We've looked at a few, right? 2 A. No. We looked at a number of 3 different studies. You know, there are both 4 positive and negative results depending on the 5 tissue or organs being looked at and depending on 6 the study. It's a mixed bag. 7 Q. So since the dietary literature is a 8 mixed bag, as you called it, what methodology did 9 you employ to make the leap from an association 10 between NDMA and cancer in some studies and 11 causation? 12 MR. SLATER: Objection. 13 Foundation. 14 You can answer. 15 A. I take into consideration the high 16 carcinogenicity of NDMA in animal models able to 17 induce tumors and I think something like 28 18 different animal species, even at very low doses 19 as shown in rats. I combine that with the study 20 design of the prospective studies and the very 21 reliable dietary information on NDMA in food and I 22 conclude that this is collectively a very strong 23 link. 24 Q. Are you familiar with the Bradford 25 Hill criteria?</p>

<p style="text-align: right;">Page 249</p> <p>1 A. Yes.</p> <p>2 Q. Do you recognize that the Bradford</p> <p>3 Hill criteria is a recognized methodology that's</p> <p>4 used to evaluate whether an observed association</p> <p>5 rises to the level of causation?</p> <p>6 A. Yes.</p> <p>7 Q. Are you familiar with the actual</p> <p>8 Bradford Hill criteria?</p> <p>9 A. Yes.</p> <p>10 Q. Can you cite any of them for me?</p> <p>11 A. I don't have them memorized, but we</p> <p>12 could pull it up if necessary.</p> <p>13 Q. It's not a memory test. I was just</p> <p>14 asking if you know any --</p> <p>15 A. Thank you.</p> <p>16 Q. -- offhand.</p> <p>17 A. Consistency is one of them.</p> <p>18 Q. There's nine of them total, right?</p> <p>19 A. I thought you said it wasn't a memory</p> <p>20 test.</p> <p>21 Q. It's not. I'm just asking if you</p> <p>22 know the number of them.</p> <p>23 A. So why don't you just pull it up then</p> <p>24 if you want to talk about it?</p> <p>25 Q. Did you employ the Bradford Hill</p>	<p style="text-align: right;">Page 251</p> <p>1 field evolve. I'm familiar with the evolution of</p> <p>2 all of the animal data and the evolution of all of</p> <p>3 the analytical chemistry data which in the early</p> <p>4 days was plagued by artifacts and other problems,</p> <p>5 but now is known to be extremely reliable.</p> <p>6 So when I put all of this data</p> <p>7 together and looking at it in comparison, looking</p> <p>8 at it in context of the firm highly reliable data</p> <p>9 that we have, put that together with the use of an</p> <p>10 epidemiologic study design, with the cohort study,</p> <p>11 I'm quite confident in the results of these</p> <p>12 studies and after having reviewed them all, my</p> <p>13 conclusion is that yes, there is definitely</p> <p>14 causation. That's my conclusion.</p> <p>15 Q. And your conclusion was based on the</p> <p>16 fact that you're familiar with the literature and</p> <p>17 you're familiar with nitrosamines, right?</p> <p>18 A. More than familiar. I would say that</p> <p>19 I have lived nitrosamines for more than half my</p> <p>20 life.</p> <p>21 Q. So you drew conclusions from the</p> <p>22 literature based on your -- given that you're</p> <p>23 familiar with it and experienced in the subject?</p> <p>24 A. Yes.</p> <p>25 Q. But you did not follow any recognized</p>
<p style="text-align: right;">Page 250</p> <p>1 criteria in this case or utilize the Bradford Hill</p> <p>2 criteria to determine whether the strength of</p> <p>3 association in some of these studies merited</p> <p>4 making the leap to causation?</p> <p>5 A. No, I did not.</p> <p>6 Q. Did you use any methodology that's</p> <p>7 described in the scientific literature to assist</p> <p>8 you in making your causation determination or was</p> <p>9 it simply your own methodology?</p> <p>10 A. I'm familiar with the methodology for</p> <p>11 the analysis of nitrosamine in foods and I know</p> <p>12 that there are very good, very thorough databases</p> <p>13 on nitrosamines in food.</p> <p>14 I'm familiar with the methodology</p> <p>15 used in epidemiology prospective so-called cohort</p> <p>16 studies. I'm familiar with those things and I'm</p> <p>17 also familiar with the animal data on nitrosamines</p> <p>18 and the dose response data for dimethyl and</p> <p>19 several other nitrosamines from animal studies.</p> <p>20 So I'm very familiar with all of this literature.</p> <p>21 It doesn't -- it's not something that</p> <p>22 I just started reading about, you know, to prepare</p> <p>23 for this deposition. This is something I have</p> <p>24 been involved with for more than 45 years, so I'm</p> <p>25 quite familiar with the field. I watched the</p>	<p style="text-align: right;">Page 252</p> <p>1 methodology for making the leap from association</p> <p>2 to causation?</p> <p>3 A. It was not a formal --</p> <p>4 MR. SLATER: Objection.</p> <p>5 One second, Doctor. Doctor, one</p> <p>6 second.</p> <p>7 Objection. That's a gross</p> <p>8 mischaracterization and it's argumentative at</p> <p>9 this point.</p> <p>10 Do you want him to walk through his</p> <p>11 methodology again for you, Counsel --</p> <p>12 MR. TRISCHLER: Sara, did you get the</p> <p>13 answer?</p> <p>14 MR. SLATER: Let me finish, please.</p> <p>15 -- or do you want to keep saying</p> <p>16 things regardless of what you heard?</p> <p>17 MR. TRISCHLER: Sara, did you get the</p> <p>18 answer?</p> <p>19 (Whereupon, the record was read back</p> <p>20 by the reporter.)</p> <p>21 Q. Did you want to finish that answer,</p> <p>22 Doctor?</p> <p>23 A. It was not a formal evaluation.</p> <p>24 Q. In your view of this case and based</p> <p>25 on your knowledge of all the relevant literature</p>

<p style="text-align: right;">Page 253</p> <p>1 which you've told us that you have, did you find a 2 single epidemiological study that concluded that 3 exogenous intake of NDMA was the cause of bladder 4 cancer in humans? 5 MR. SLATER: Objection. 6 A. Bladder cancer? I don't think I saw 7 bladder cancer. 8 Q. In your review -- 9 A. I don't think that's been reported. 10 Q. In your review of all the literature, 11 did you find a single peer review study that 12 concluded that exogenous intake of NDMA was the 13 cause of blood cancer in humans? 14 A. No. 15 Q. In your review of all the literature, 16 did you find a single peer-reviewed study that 17 concluded that exogenous intake of NDMA was the 18 cause of breast cancer in humans? 19 A. No. 20 Q. In your review of all the literature, 21 did you find a single peer-reviewed study that 22 concluded that exogenous intake of NDMA was the 23 cause of colorectal cancer in humans? 24 A. Yes. 25 Q. My question was cause, not</p>	<p style="text-align: right;">Page 255</p> <p>1 Q. Are you aware of any peer-reviewed 2 published study that concluded that exogenous 3 intake of NDMA was the cause of gastric cancer in 4 humans? 5 A. Cause? No. 6 Q. Are you aware of any peer-reviewed 7 study that concluded that exogenous intake of NDMA 8 was the cause of kidney cancer in humans? 9 A. No. 10 Q. Are you aware of any peer-reviewed 11 study that concluded that exogenous intake of NDMA 12 was the cause of liver cancer in humans? 13 A. No. 14 Q. Are you aware of any peer-reviewed 15 studies that concluded that exogenous intake of 16 NDMA was the cause of lung cancer in humans? 17 A. No. Not cause, no. 18 Q. Are you aware of any peer-reviewed 19 study that concluded that exogenous intake of NDMA 20 was the cause of pancreatic cancer in humans? 21 A. No. 22 Q. Are you aware of any peer-reviewed 23 study that concluded that the exogenous intake of 24 NDMA was the cause of pharyngeal cancer in humans? 25 A. No.</p>
<p style="text-align: right;">Page 254</p> <p>1 association. 2 Did you find any papers that 3 suggested that exogenous intake of NDMA was the 4 cause of colorectal cancer in humans? 5 A. We just reviewed -- we just did this. 6 I mean, I don't know. I don't know what you're 7 getting at here. 8 Q. I'm distinguishing between -- 9 A. We just did this and we just 10 discussed all of this, so I don't know what you're 11 trying to get at. 12 Q. Well, let me try and help you out, if 13 I can. I'm distinguishing between a study that 14 notes an association and a published study that 15 makes a determination or statement regarding 16 cause. 17 So my question is are you aware of 18 any peer-reviewed study that concluded that 19 exogenous intake of NDMA was the cause of 20 colorectal cancer in humans? 21 A. No. 22 Q. Are you aware of any published study 23 that concluded that exogenous intake of NDMA was 24 the cause of esophageal cancer in humans? 25 A. No.</p>	<p style="text-align: right;">Page 256</p> <p>1 Q. Are you aware of any peer-reviewed 2 study that concluded that exogenous intake was the 3 cause of -- exogenous intake of NDMA was the cause 4 of prostate cancer in humans? 5 A. No. 6 Q. Are you aware of any peer-reviewed 7 study that concluded that the exogenous intake of 8 NDMA was the cause of uterine cancer in humans? 9 A. No. 10 Q. I'm going to ask you a questions now 11 about NDEA as opposed to NDMA. 12 A. It's all the same answers. You don't 13 have to go through it. 14 Q. If we listed all 13 of the cancers 15 that are at issue, are you aware of any 16 peer-reviewed study that concluded that exogenous 17 intake of NDEA was the cause of any of those 18 cancers? 19 A. No. 20 Q. Do you agree or disagree with this 21 statement, Doctor: DNA adduct formation alone is 22 inadequate to confirm mutation or cancer? 23 A. Agree. 24 MR. SLATER: Objection. 25 You went a little quick again.</p>

<p style="text-align: right;">Page 257</p> <p>1 Are we going back over this again? I</p> <p>2 thought we --</p> <p>3 MR. TRISCHLER: You cut out, Adam. I</p> <p>4 couldn't hear you.</p> <p>5 MR. SLATER: Can you hear me now?</p> <p>6 MR. TRISCHLER: Yes.</p> <p>7 MR. SLATER: I said objection.</p> <p>8 I thought we covered this hours ago.</p> <p>9 Q. Are you familiar with MGMT?</p> <p>10 A. Yes.</p> <p>11 Q. Is MGMT a DNA repair enzyme?</p> <p>12 A. Yes.</p> <p>13 Q. Is it one of those things in our body</p> <p>14 that allows us to fight off mutagens?</p> <p>15 A. No, it doesn't act on mutagens. It</p> <p>16 acts on DNA adducts, specifically</p> <p>17 O6-methylguanine. So O6-methylguanine DNA methyl</p> <p>18 transfers. Therefore the name MGMT.</p> <p>19 Q. Do you agree or disagree with this</p> <p>20 statement: Risks from nitrosamines in drugs is</p> <p>21 likely to be very low because depletion of MGMT is</p> <p>22 not expected?</p> <p>23 A. I don't necessarily agree with that,</p> <p>24 no.</p> <p>25 Q. What would be your --</p>	<p style="text-align: right;">Page 259</p> <p>1 adducts in DNA. O6-methylguanine has been studied</p> <p>2 most extensively because we know that it has</p> <p>3 miscoding properties. We know that it can lead to</p> <p>4 mutations. We know about MGMT, we know that it's</p> <p>5 -- well, it's not the major DNA damage caused by</p> <p>6 nitrosamines by any means. It's actually one of</p> <p>7 the minor ones. So there's a lot of other damaged</p> <p>8 DNA that can lead to mutations and cancer. It</p> <p>9 wouldn't be addressed by MGMT.</p> <p>10 Q. Have you ever studied MGMT depletion</p> <p>11 in humans?</p> <p>12 A. No, I honestly have not studied it.</p> <p>13 My group has not studied it. There's a fair</p> <p>14 amount of literature on it. There's a large</p> <p>15 amount of literature on it, particularly in the</p> <p>16 chemotherapy literature because MGMT can act on</p> <p>17 chemotherapeutic drugs, decreasing their efficacy,</p> <p>18 so people looked for inhibitors of MGMT to be used</p> <p>19 as co-factors in chemotherapy.</p> <p>20 Q. I want to go back and do a little</p> <p>21 housekeeping, just to make sure that I have an</p> <p>22 understanding of everything that you reviewed and</p> <p>23 relied upon to put together your report and come</p> <p>24 to your conclusions.</p> <p>25 Okay?</p>
<p style="text-align: right;">Page 258</p> <p>1 A. I don't agree with that.</p> <p>2 Q. What would be your basis for</p> <p>3 disagreeing?</p> <p>4 A. Well, MGMT activity might be low for</p> <p>5 a number of reasons. It may have been MGMT</p> <p>6 activity may have been used up by other exposures,</p> <p>7 so, you know, if there is O6-alkylguanine form</p> <p>8 from various different exposures, some of which we</p> <p>9 may not be aware of, MGMT can be used up tending</p> <p>10 to those exposures.</p> <p>11 Q. Do you --</p> <p>12 A. So I don't think we know -- we don't</p> <p>13 really know, you know, how much MGMT activity a</p> <p>14 person has in reserve to address nitrosamine</p> <p>15 exposure. We don't have that information.</p> <p>16 Q. So long as there's no MGMT depletion,</p> <p>17 one would not expect that a low-level nitrosamine</p> <p>18 exposure would lead to the development of</p> <p>19 mutagens, correct?</p> <p>20 MR. SLATER: Objection.</p> <p>21 You can answer.</p> <p>22 A. No, I don't think that's correct. I</p> <p>23 mean, nitrosamines do a lot of things to DNA.</p> <p>24 It's not just O6-methylguanine.</p> <p>25 Dimethylnitrosamine forms multiple different</p>	<p style="text-align: right;">Page 260</p> <p>1 A. Okay.</p> <p>2 Q. You -- we talked about how you were</p> <p>3 retained by --</p> <p>4 MR. SLATER: Counsel, excuse me, I</p> <p>5 don't mean to interrupt, but are you now</p> <p>6 going to rehash the testimony from six hours</p> <p>7 ago? I don't understand what we're doing.</p> <p>8 MR. TRISCHLER: You probably couldn't</p> <p>9 understand what I'm doing since I haven't</p> <p>10 asked a question yet.</p> <p>11 MR. SLATER: Well, no, but you</p> <p>12 started to ask about, you know, you're back</p> <p>13 to the beginning. I don't think it's a</p> <p>14 reasonable predicate to say "Well, I just</p> <p>15 want to make sure I understand ..." and then</p> <p>16 go over testimony you took in great detail in</p> <p>17 the questioning. I ask you not to duplicate</p> <p>18 that questioning, please.</p> <p>19 MR. TRISCHLER: Well, since I haven't</p> <p>20 asked a question yet, I don't know how it</p> <p>21 could be duplicative, but if you think it is,</p> <p>22 I'm sure you could object to it on that</p> <p>23 basis.</p> <p>24 MR. SLATER: Well, it's your</p> <p>25 obligation not to do so, so don't put it on</p>

<p style="text-align: right;">Page 261</p> <p>1 me, please.</p> <p>2 Q. You told us that you reviewed</p> <p>3 documents that were provided to you by counsel.</p> <p>4 Do you recall that?</p> <p>5 A. Yes.</p> <p>6 MR. TRISCHLER: I'm going to mark as</p> <p>7 an exhibit the next number that we're up to,</p> <p>8 a document that I think was attached to your</p> <p>9 report. It's called "Documents Reviewed" and</p> <p>10 it's Exhibit 2 to your report. I'm going to</p> <p>11 mark it as a separate exhibit here.</p> <p>12 Can you put that up, Bill, please?</p> <p>13 THE VIDEOGRAPHER: Just looking for a</p> <p>14 document that matches that description.</p> <p>15 Just give me one moment.</p> <p>16 THE WITNESS: It's B. It's addendum</p> <p>17 B.</p> <p>18 THE VIDEOGRAPHER: I'm seeing a</p> <p>19 document that was uploaded. The name of the</p> <p>20 document is reviewed -- got it. Sorry about</p> <p>21 that. That will be Exhibit 19.</p> <p>22 (Whereupon, Exhibit 19 was marked for</p> <p>23 identification.)</p> <p>24 Q. This is a document that you prepared</p> <p>25 and provided in connection with your report,</p>	<p style="text-align: right;">Page 263</p> <p>1 marked as Exhibit 1?</p> <p>2 A. No. The list is complete.</p> <p>3 Q. I was told that you also -- it was</p> <p>4 delivered to me yesterday, six binders of</p> <p>5 materials that was delivered to me electronically</p> <p>6 and there was a table of contents with those</p> <p>7 binders.</p> <p>8 Have you ever seen those tables of</p> <p>9 contents?</p> <p>10 A. I think I know what you're referring</p> <p>11 to. I mean, in the binders, the binders have a</p> <p>12 table of contents.</p> <p>13 MR. TRISCHLER: I don't know if we</p> <p>14 have these in the chat or available, but I</p> <p>15 was going to mark the table of contents in</p> <p>16 the binder as the next number of exhibit,</p> <p>17 just so we have a record of what his file</p> <p>18 materials consist of. Okay?</p> <p>19 MR. SLATER: Yeah, I mean all those</p> <p>20 materials you have already and have had.</p> <p>21 Those were just provided to him for his</p> <p>22 convenience, in case he wanted to look at</p> <p>23 them. You can mark them --</p> <p>24 MR. TRISCHLER: Right. I understand</p> <p>25 that. I understand, but it's a nice handy</p>
<p style="text-align: right;">Page 262</p> <p>1 correct, sir?</p> <p>2 A. Yes.</p> <p>3 Q. All I'm trying to confirm is is this</p> <p>4 a list of documents that were provided to you by</p> <p>5 counsel in connection with your review and your</p> <p>6 work in this case?</p> <p>7 A. Yes.</p> <p>8 Q. I think that -- and to be fair, when</p> <p>9 we get to the last -- the second-to-last page,</p> <p>10 there's a section marked "Regulatory Documents"</p> <p>11 and you had indicated before that, you know, in</p> <p>12 addition to looking at company documents and the</p> <p>13 public literature, you also looked at public</p> <p>14 materials about the valsartan medications,</p> <p>15 correct?</p> <p>16 A. Yes.</p> <p>17 Q. Would this be a list of those public</p> <p>18 documents that you reviewed?</p> <p>19 A. Yes.</p> <p>20 Q. Is there -- other than what's on this</p> <p>21 six-page list -- and please feel free to go</p> <p>22 through it if you need -- but are there any other</p> <p>23 documents that you reviewed or received in</p> <p>24 connection with your work in this case prior to</p> <p>25 the time you sat down and wrote the report that we</p>	<p style="text-align: right;">Page 264</p> <p>1 reference of what the contents of his file</p> <p>2 were, so I was going to mark them as a</p> <p>3 numbered exhibit, if that's okay.</p> <p>4 MR. SLATER: Well, yeah, I'm not</p> <p>5 going to tell you that's all the materials in</p> <p>6 his file, though, because I don't know that</p> <p>7 it is. I don't think it is. I don't think</p> <p>8 we printed everything. So I don't think</p> <p>9 that's going to -- his file is -- I mean, you</p> <p>10 have everything. I just can't tell you those</p> <p>11 table of contents is everything because I</p> <p>12 don't think we sent him everything.</p> <p>13 MR. TRISCHLER: Fair enough.</p> <p>14 (Whereupon, Exhibit 20 was marked for</p> <p>15 identification.)</p> <p>16 BY MR. TRISCHLER:</p> <p>17 Q. Dr. Hecht, I'm just trying to -- what</p> <p>18 I'm obviously interested is in knowing everything</p> <p>19 you may have read, reviewed and relied upon.</p> <p>20 Do you have the tables of contents</p> <p>21 for the binders in front of you?</p> <p>22 A. Yes.</p> <p>23 Q. Can you take a look at those and tell</p> <p>24 me whether those tables of contents contain the</p> <p>25 documents and literature that you relied upon?</p>

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1 MR. SLATER: I'm sorry, Clem. You're
2 asking him to do it? He's going to have to
3 sit there and walk through it, compare it to
4 the "Materials Reviewed" list and his whole
5 report? Is that what you're asking him to
6 do?
7 MR. TRISCHLER: I don't really want
8 him to do that, Adam --
9 MR. SLATER: But, I mean, you have it
10 attached to the report, you have the
11 references in the report, so you can mark the
12 tables of contents, you can do whatever you
13 want, I'm just not really sure what we're
14 getting at. You have the tables of contents.
15 Is there something on those tables of
16 contents that you think wasn't in the report?
17 You can tell us and ask him the question, but
18 I don't think so.
19 MR. TRISCHLER: I guess that's the
20 question. Let me ask that question.
21 Q. Do you know if there's anything
22 listed on the tables of contents in these binders
23 that were not cited in your report?
24 MR. SLATER: You want him -- you want
25 him to go through and compare everything? I

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1 mean, I'm told by Chris that he thinks that
2 the tables of contents are pretty
3 comprehensive, if not everything. But I just
4 can't swear to it right now. Short of him
5 comparing everything, how else is he going to
6 be sure?
7 MR. TRISCHLER: I didn't get the
8 binders until yesterday. I didn't get a
9 chance to look at them. I'm just trying --
10 MR. SLATER: Clem, we gave those
11 binders as a courtesy because they're not new
12 materials. They're all things you already
13 had.
14 MR. TRISCHLER: And I'm not
15 complaining, Adam. I'm trying to figure out
16 whether there's anything on here that I
17 haven't seen or hasn't been identified
18 before. I don't think that's an improper
19 question.
20 MR. SLATER: No, but I'm saying
21 wouldn't it be easier to have someone in your
22 office go down the list and compare to the
23 report and see if there's anything new?
24 MR. TRISCHLER: Well, perhaps, but I
25 wasn't smart enough to do that.

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1 MR. SLATER: That's not -- I'm not
2 being nasty, so I don't need that comment.
3 MR. TRISCHLER: I didn't suggest you
4 were being nasty.
5 MR. SLATER: Look, you use the time
6 any way you want.
7 Do you know yet if anyone else plans
8 to follow up after you because we are
9 probably at seven hours now?
10 MR. TRISCHLER: I don't how long
11 we're into it and I don't know the answer to
12 that question, but let's just see if we could
13 get this done and then we'll move on to
14 something else.
15 THE VIDEOGRAPHER: Counsel, sorry to
16 cut it. Just to let you know, I don't have
17 a document, the table of contents --
18 MR. TRISCHLER: I know you don't. I
19 already said that you don't have it.
20 THE VIDEOGRAPHER: I'm saying if you
21 want to send it to me later on, I can mark
22 that as the next exhibit.
23 MR. TRISCHLER: Right.
24 THE VIDEOGRAPHER: And we have about
25 seven minutes on this media, just so you

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1 know.
2 Thank you.
3 BY MR. TRISCHLER:
4 Q. Do you know offhand, Doctor -- and I
5 don't know how much time you spent with the
6 binder -- do you know offhand whether there's
7 anything in the binders that is not identified in
8 the documents reviewed that we marked as the last
9 exhibit and the references that are mentioned in
10 the report?
11 A. No. I mean, offhand, you know, the
12 binders contain what's in the report.
13 Q. Is there any work that you've done
14 since preparing your report in this case?
15 A. What do you mean by work?
16 Q. Well, I mean --
17 A. I had to review all of the material.
18 I mean, that's work.
19 Q. Sure. Fair enough.
20 Other than reviewing the material, is
21 there any new work that you did, any new studies
22 that you looked at, any additional research that
23 you've done since you wrote this report in July?
24 A. No. Not relevant to this case.
25 Q. As part of your work in this case,

<p style="text-align: right;">Page 269</p> <p>1 have you reviewed the reports of other experts 2 that were retained by the plaintiffs in this 3 litigation? 4 A. No, not the reports. I did see some 5 transcripts of, you know, parts of testimony, but 6 not -- I didn't review the report, I haven't 7 reviewed any of the reports. 8 Q. I'll represent to you that the 9 depositions of the experts for the plaintiff are 10 only taking place recently, so that's including 11 your deposition obviously. 12 I'm looking at the list of deposition 13 testimony that you reviewed that's part of our 14 last numbered exhibit and -- 15 A. No, I didn't review those. I don't 16 know why that's there. I haven't seen them. I 17 haven't seen those. 18 MR. SLATER: Dr. Hecht, can you wait 19 until he asks you a question, please? He 20 hasn't asked you yet. He's moved off the 21 expert reports. He's onto something new now. 22 Q. You've not reviewed any expert 23 reports from any other expert in the case; true? 24 A. No. True. 25 Q. You've not seen any of the deposition</p>	<p style="text-align: right;">Page 271</p> <p>1 Q. Sure. 2 When's the last time you gave a 3 deposition or other sworn testimony under oath? 4 A. I don't remember the exact date, but 5 I believe it was about ten years ago in a case 6 involving smokeless tobacco and cancer. I'm not 7 sure of the exact date. 8 Q. Were you working as an expert witness 9 in this case ten years ago? 10 A. Yes. 11 Q. In connection with your expert work 12 where you've been asked to give depositions or 13 give deposition testimony, has all of it been in 14 cases involving tobacco? 15 A. Yes. 16 Q. I guess another way of asking the 17 same question, just to make sure I understand and 18 get the complete answer, have you ever been 19 involved in a litigation matter as an expert 20 witness that did not involve tobacco? 21 A. No. 22 Q. Have you ever testified at trial as 23 an expert witness? 24 A. No. No. 25 MR. TRISCHLER: This would be a good</p>
<p style="text-align: right;">Page 270</p> <p>1 transcripts from any of the experts in the case? 2 A. Correct. 3 Q. You've not spoken to any of the other 4 experts retained by plaintiff? 5 A. Correct. 6 Q. And I take it that you're not relying 7 upon any other expert retained by plaintiff to 8 support any of your opinions in this case? 9 A. Correct. 10 Q. I asked you before about medical 11 records and you told me you haven't reviewed any 12 patient medical records. 13 Have you reviewed any pathology 14 slides or tissue samples for any plaintiff? 15 A. No. 16 Q. Have you reviewed any of the reports 17 of any of the defense experts in this case? 18 A. No. 19 Q. Do you know who any of the defense 20 experts are? 21 A. No, I do not. 22 Q. When's the last time you gave a 23 deposition or sworn testimony under oath? 24 A. Repeat the question, please. I 25 didn't hear the whole thing.</p>	<p style="text-align: right;">Page 272</p> <p>1 time for me to go into another area and I'm 2 getting near completion. 3 Can we take a five-minute break, 4 Adam, and if you want, I can roundtable with 5 my colleagues and see who we have as 6 questioning and how much? 7 MR. SLATER: Okay. Obviously with 8 the caution that there shouldn't be any 9 duplicative questioning obviously. 10 That's not for your benefit -- 11 MR. TRISCHLER: I don't think any 12 that's the intent of anybody, but I 13 understand your position. 14 Why don't we take ten minutes? It'll 15 give me a chance to look at the rest of what 16 I want to do and then I can get some -- at 17 least some electronic feedback from our side 18 as to what else people think. 19 Okay? 20 MR. SLATER: Sounds good. 21 THE VIDEOGRAPHER: The time is 4:27. 22 This concludes media four. 23 (Recess taken) 24 THE VIDEOGRAPHER: The time is now 25 4:38.</p>

<p style="text-align: right;">Page 273</p> <p>1 This begins media five.</p> <p>2 You may proceed.</p> <p>3 Q. Dr. Hecht, are you familiar with the</p> <p>4 Pottegård study?</p> <p>5 A. Pottegård?</p> <p>6 MR. SLATER: Which study did you say,</p> <p>7 Clem? I missed that.</p> <p>8 MR. TRISCHLER: Pottegård.</p> <p>9 A. I am.</p> <p>10 Q. I'll give you a second to grab</p> <p>11 whatever you're looking for. Are you pulling up a</p> <p>12 copy of the study?</p> <p>13 A. Yeah, I am.</p> <p>14 Okay. That's the Danish --</p> <p>15 (Whereupon, Exhibit 21 was marked for</p> <p>16 identification.)</p> <p>17 Q. Right. Yes, sir. We'll mark the</p> <p>18 Pottegård study as the next numbered exhibit. You</p> <p>19 don't have to show it. The witness has it in</p> <p>20 front of him.</p> <p>21 In this Pottegård paper, the authors</p> <p>22 followed about 5,150 Danish patients who used</p> <p>23 valsartan, correct?</p> <p>24 A. Yes.</p> <p>25 Q. And I think what the paper tells us</p>	<p style="text-align: right;">Page 275</p> <p>1 I guess that's true. It's a very broad statement.</p> <p>2 We do experimental studies here that</p> <p>3 I don't really think have any limitations. When</p> <p>4 you're talking about studies of populations, then</p> <p>5 the limitations become more -- there can be more</p> <p>6 limitations.</p> <p>7 Q. In any event, what Pottegård reported</p> <p>8 was that there was no evidence of a markedly</p> <p>9 increased short term overall risk of cancer from</p> <p>10 the valsartan containing NDMA, correct?</p> <p>11 A. Yes.</p> <p>12 Q. You cite Pottegård in your report</p> <p>13 that you prepared for this case, right?</p> <p>14 A. Yes.</p> <p>15 Q. And when you prepared this report</p> <p>16 back in July, did you understand that it was going</p> <p>17 to be filed with the Federal MDL Court?</p> <p>18 A. Federal MDL Court is what?</p> <p>19 Q. That's the court --</p> <p>20 A. I don't think so. I'm not sure I</p> <p>21 know what you're talking about.</p> <p>22 Q. I'm trying to tell you, explain it to</p> <p>23 you.</p> <p>24 It's the court where this litigation</p> <p>25 is based. Did you understand that this report was</p>
<p style="text-align: right;">Page 274</p> <p>1 is that the scientists who did this study followed</p> <p>2 these individuals for a median of 4.6 years and</p> <p>3 examined cancer rates in valsartan users as</p> <p>4 compared to a cohort of non-valsartan users,</p> <p>5 right?</p> <p>6 A. Yes.</p> <p>7 Q. Based on your review of this study,</p> <p>8 was it a good, well-designed study?</p> <p>9 A. Well, you know, the follow up -- the</p> <p>10 sample size was pretty small and the follow up is</p> <p>11 also pretty small. So I mean as an initial pass</p> <p>12 at the problem, and, you know, the effects of the</p> <p>13 NDMA in tablets, I guess it was okay. But, I</p> <p>14 mean, it's a relatively small study and the follow</p> <p>15 up is not very long, so it's not too surprising</p> <p>16 that it didn't find anything. So, you know, a</p> <p>17 negative study doesn't really prove anything.</p> <p>18 Q. So as with all studies, there were</p> <p>19 some limitations to it?</p> <p>20 A. I wouldn't say all studies. That's a</p> <p>21 very broad statement.</p> <p>22 Q. I thought you said that all studies</p> <p>23 have limitations?</p> <p>24 A. Maybe I said that, but not all</p> <p>25 studies. Well, all studies have some limitations.</p>	<p style="text-align: right;">Page 276</p> <p>1 going to be filed with the court?</p> <p>2 A. Yes.</p> <p>3 Q. And did you put together the report</p> <p>4 as a summary of the scientific basis for the</p> <p>5 opinions that you were offering?</p> <p>6 A. Yes.</p> <p>7 Q. Do you agree that a report of this</p> <p>8 nature should not misstate or misrepresent the</p> <p>9 state of clients as reflected in the literature?</p> <p>10 A. Yes.</p> <p>11 Q. I assume you'd agree with me that</p> <p>12 scientists are not supposed to take liberties in</p> <p>13 preparing reports of this nature, correct?</p> <p>14 A. I don't know what you mean by "take</p> <p>15 liberties."</p> <p>16 Q. Well, stretching the truth or</p> <p>17 distorting findings is not what a scientist is</p> <p>18 supposed to do.</p> <p>19 Can we agree on that?</p> <p>20 A. We never stretch the truth or distort</p> <p>21 findings.</p> <p>22 Q. And so when you cite to Pottegård in</p> <p>23 your report -- strike that.</p> <p>24 When you put this report together,</p> <p>25 you already told me that one of the questions that</p>

<p style="text-align: right;">Page 277</p> <p>1 was at the heart of this was whether or not NDMA 2 can cause cancer in humans, correct? 3 A. Yes. 4 Q. So when you cite to -- here, we have 5 a study like Pottegård that aims to answer that 6 very question, right? 7 A. Yes. 8 Q. When you cite to Pottegård in your 9 report, you make no mention at all of the authors' 10 conclusion that NDMA in valsartan was not found to 11 increase the short term overall risk of cancer? 12 A. No. 13 Q. Right? Never mention that? 14 MR. SLATER: Objection. 15 You can answer. 16 A. That's what you say. 17 Q. Well, it's what I say, but it's 18 truthful, right? You never mention it in your 19 report -- 20 A. Okay. 21 Q. -- what Pottegård included? 22 A. All right. That's an oversight. I 23 should have mentioned it. 24 Q. Because that's an important 25 observation obviously, right?</p>	<p style="text-align: right;">Page 279</p> <p>1 risk of cancer associated with the use of 2 valsartan with NDMA from your report? 3 MR. SLATER: Objection to the 4 terminology and foundation. 5 You can answer. 6 A. I guess I have to find the page where 7 the -- 8 Q. Sure. I can help you -- 9 A. -- Pottegård is discussed, so I see 10 exactly what I said here. What page is it? 11 Q. Page 16 is where I see it, both in 12 the first full paragraph and the last. 13 A. Yeah, I summarize the EMA comments. 14 EMA statement cites and discusses a study 15 performed in Denmark. That's the Pottegård study. 16 I'm a little confused here. Yeah. 17 So what's your question? What is your question? 18 Q. Why did you make no mention of 19 Pottegård's conclusion that NDMA in valsartan did 20 not lead to an increased short term overall risk 21 of cancer? 22 A. Well, I guess I took the NDMA 23 valuation of the 4.6 year follow-up interval was 24 likely too short, so I didn't discuss it further 25 than that. I might have -- might have discussed</p>
<p style="text-align: right;">Page 278</p> <p>1 MR. SLATER: Objection. 2 A. It's a preliminary observation. I 3 don't know if it's really an important 4 observation. 5 Q. It's something an objective scientist 6 would want to disclose, don't you think? 7 MR. SLATER: Objection. 8 Wait. Time out, Dr. Hecht. 9 Objection. 10 Argumentative. 11 Do you have a question, rather than 12 just making statements at the witness? 13 MR. TRISCHLER: I just asked it and 14 he just answered it. 15 MR. SLATER: Yeah, but you didn't 16 ask. You're just throwing statements at him 17 instead of asking the question. 18 Do you have a question about 19 Pottegård? Do you have a question about 20 something? 21 MR. TRISCHLER: I have another one 22 that I'll ask as soon as you're done. 23 BY MR. TRISCHLER: 24 Q. Why did you omit Pottegård's 25 conclusion that there was no short term overall</p>	<p style="text-align: right;">Page 280</p> <p>1 it more. 2 Q. Well, what you did cite to with 3 respect to Pottegård was you make a suggestion at 4 page 16 that the study found an increased risk for 5 colorectal cancer and uterine cancer. 6 Do you see that at page 16? 7 A. Yes, I see that. 8 MR. SLATER: That's the only 9 question, Doctor. Did you -- 10 A. I'm a little puzzled by that. 11 Q. Is that an accurate statement? Is 12 that what Pottegård actually found? 13 A. In the analysis of single cancer 14 outcomes, increased risks were seen for colorectal 15 cancer and for uterine cancer, although neither 16 these, nor other single cancer outcomes reached 17 statistical significance. 18 So yeah, that was the outcome. It 19 wasn't -- so it's -- it's not exactly right, 20 what's written here. It's a little unclear. It's 21 not that clear. 22 Q. "Not exactly right" -- 23 A. I should have -- I should have -- I 24 should have been more clear in the way I wrote 25 this.</p>

<p style="text-align: right;">Page 281</p> <p>1 Q. "Not exactly right" is a kind way of</p> <p>2 saying what you wrote is incorrect?</p> <p>3 MR. SLATER: Objection.</p> <p>4 Q. If you look at the results on the</p> <p>5 first page of the study, what Pottegård wrote was</p> <p>6 that the confidence intervals for the single</p> <p>7 outcome cancers were so wide as to include the</p> <p>8 null, so no conclusions could be drawn, right?</p> <p>9 A. Yes.</p> <p>10 Q. Looking at it now, what we can say is</p> <p>11 that Pottegård never found a statistically</p> <p>12 significant increased risk of colorectal cancer,</p> <p>13 did he?</p> <p>14 A. No.</p> <p>15 Q. He never found a statistically</p> <p>16 significant increased risk of uterine cancer, did</p> <p>17 he?</p> <p>18 A. That's correct.</p> <p>19 Q. Those are obviously important</p> <p>20 observations that were never mentioned in your</p> <p>21 report either, correct?</p> <p>22 MR. SLATER: Objection.</p> <p>23 You can answer.</p> <p>24 A. It's an oversight that should have</p> <p>25 been mentioned.</p>	<p style="text-align: right;">Page 283</p> <p>1 did you find Gomm to be a good study?</p> <p>2 A. I found out to be remarkable in the</p> <p>3 sense that they sought excessive liver cancer.</p> <p>4 Q. Did you find the conclusions in this</p> <p>5 study reliable?</p> <p>6 A. Yes, but it needs confirmation.</p> <p>7 Q. Gomm reached the same conclusion as</p> <p>8 Pottegård. In a national study, there was no</p> <p>9 evidence of an increase in the overall risk of</p> <p>10 cancer amongst valsartan users, correct?</p> <p>11 A. Overall, yeah. But they did find a</p> <p>12 risk -- an increased risk of liver cancer.</p> <p>13 Q. We'll talk about that in a minute.</p> <p>14 In terms of the overall risk of</p> <p>15 cancer, Gomm found no evidence of such an</p> <p>16 increased risk; true?</p> <p>17 A. Correct.</p> <p>18 Q. The conclusion is Pottegård, correct?</p> <p>19 A. Yes.</p> <p>20 Q. So we have two national studies done</p> <p>21 by two different groups of scientists, both</p> <p>22 concluding that NDMA in valsartan did not lead to</p> <p>23 an increased overall risk of cancer; true?</p> <p>24 A. Well, I think the follow up would</p> <p>25 have to be much longer. You know, these are</p>
<p style="text-align: right;">Page 282</p> <p>1 Q. You also cite to the Gomm study in</p> <p>2 your report on page 16, right?</p> <p>3 A. Yes.</p> <p>4 Q. Do you have that with you, sir, and</p> <p>5 available to you?</p> <p>6 A. I do.</p> <p>7 MR. TRISCHLER: We'll mark the Gomm</p> <p>8 study the next numbered exhibit.</p> <p>9 Bill, you do not have to display it</p> <p>10 since the witness has it in front of him.</p> <p>11 (Whereupon, Exhibit 22 was marked for</p> <p>12 identification.)</p> <p>13 Q. Doctor, Gomm was a study where they</p> <p>14 used the German registry database to look at over</p> <p>15 750,000 individuals who filled valsartan scripts,</p> <p>16 right?</p> <p>17 A. Yes.</p> <p>18 Q. And the incidence of cancer was</p> <p>19 compared to non-valsartan users, right?</p> <p>20 A. Yes.</p> <p>21 Q. And we talked about how most every</p> <p>22 study has limits and I assume Gomm is no</p> <p>23 exception, right?</p> <p>24 A. Sure.</p> <p>25 Q. But notwithstanding those limits,</p>	<p style="text-align: right;">Page 284</p> <p>1 both -- really, they're both preliminary studies.</p> <p>2 The follow up would have to be longer and we would</p> <p>3 need to know more about who actually took which</p> <p>4 pills, which is not addressed here.</p> <p>5 So, you know, these are -- I think</p> <p>6 these are okay as preliminary studies, but I think</p> <p>7 they're both preliminary. We need -- we would</p> <p>8 need a -- more of a follow up, for example, you</p> <p>9 wouldn't really necessarily expect to see an</p> <p>10 increase in liver cancer within three years.</p> <p>11 And the same goes for the other</p> <p>12 study. I think the follow-up time is too short</p> <p>13 and there are many -- there's many questions about</p> <p>14 both of these studies.</p> <p>15 Q. All right.</p> <p>16 Limitations aside, you would agree</p> <p>17 with me we do have two nationwide studies which</p> <p>18 both reported no increase in the overall risk of</p> <p>19 cancer.</p> <p>20 Agreed?</p> <p>21 A. Yes, but I wouldn't put the</p> <p>22 limitations aside. Limitations are there. It's</p> <p>23 obvious what they are.</p> <p>24 Q. In your report --</p> <p>25 A. I don't think you would expect an</p>

<p style="text-align: right;">Page 285</p> <p>1 increased incidence of liver cancer within three 2 years. 3 Q. In your report to this court where 4 you tried to honestly and objectively answer the 5 causation question, you never mentioned the 6 findings of either one of these studies, right? 7 MR. SLATER: Objection. 8 A. No, they're both in the report. 9 Q. No, they're not. We went through it. 10 You don't mention -- 11 MR. SLATER: Counselor, lower your 12 voice towards the witness and look at the 13 page because he just told you it's in the 14 report. You obviously haven't read page 16. 15 You're not going to attack him 16 aggressively like this. You're not going to 17 do it. You're just not going to do it. 18 Q. Sir, do you ever mention in your 19 report that Pottegård found no overall increased 20 risk of cancer? Yes or no? 21 MR. SLATER: Objection. 22 We went through this already. 23 You can answer again. 24 A. Pottegård? We already went through 25 this. Pottegård did not find a significant</p>	<p style="text-align: right;">Page 287</p> <p>1 MR. SLATER: Take your time, please. 2 A. The Gomm paper found an increased 3 risk for liver cancer was identified, but no 4 association was identified for the overall risk of 5 cancer. So yeah, it's in there. It's in there. 6 Q. All right. 7 You've talked about what Gomm 8 observed with respect to liver cancer. 9 Do you understand that valsartan is a 10 long-term-use medication? 11 A. Yes. 12 Q. Patients that are taking ARBs to 13 control hypertension don't use these medications 14 acutely, right? 15 A. Right. 16 Q. When they take valsartan or any ARB, 17 the patients tend to be on them for years, 18 correct? 19 A. Yes. 20 Q. In Gomm, when the authors adjusted 21 for long-term use, isn't it true that the data 22 could no longer find an association for liver 23 cancer? 24 MR. SLATER: Objection. 25 You can answer.</p>
<p style="text-align: right;">Page 286</p> <p>1 increase. 2 Q. Correct. 3 Am I correct -- 4 A. Did not find -- did not find a 5 significant increase. 6 Q. Correct. 7 My question is did you ever mention 8 that in your report? 9 MR. SLATER: Didn't we go through 10 that already -- 11 A. We already did that. I already told 12 you that was an oversight. It's unclear the way 13 it's written. I already told you that. I already 14 told you that. 15 Q. Gomm found no -- 16 A. You know, none of us are perfect. 17 Sometimes we make mistakes. 18 Q. I understand. 19 A. Maybe even you do. 20 MR. SLATER: Doctor, it's okay. 21 Q. Gomm found no overall increased risk 22 of cancer. 23 Did you ever mention that fact in 24 your report? 25 A. No.</p>	<p style="text-align: right;">Page 288</p> <p>1 A. I don't know. I'd have to -- I have 2 to look at it again. I'm sorry. 3 Q. Sure. 4 If you have to study in front of you, 5 you might want to take a look at page 358. 6 A. Yes. No dose-dependent effect on the 7 risk of liver cancer was found for higher 8 exposure, bearing lag times of six month to two 9 years, also did not alter the effect. Valuation 10 three year long-term use resulted in decreased 11 sample size and showed no significant association 12 with liver cancer. So that was 1.22, but it was 13 not significant. 14 So yeah, that's what they found. But 15 I mean I really think both of these studies are 16 somewhat flawed. That's my opinion. Because with 17 a low-dose dimethylnitrosamine in animals, it 18 takes time for the tumors to appear. You wouldn't 19 get them in the same kind of time scale they're 20 talking about here. Humans are far more 21 susceptible to liver cancer based on exposure to 22 dimethylnitrosamine than animals -- 23 Q. What's the -- 24 A. -- or the -- you know, the timeframe 25 I simply think is not long enough. Even in</p>

<p style="text-align: right;">Page 289</p> <p>1 tobacco and cancer, where you have a much stronger 2 carcinogen, the timeframe is minimum of 20 years. 3 Q. And that's a minimum of 20 years from 4 exposure to the carcinogen to the development of 5 the tumor? 6 A. Right. 7 Q. So, you know, anyone suggesting that 8 they got a tumor from valsartan-containing 9 medication that developed in a year or 18 months, 10 that would be highly unlikely because the time 11 period is just too short? 12 MR. SLATER: Objection. 13 You can answer. 14 A. I don't know about anyone -- okay? -- 15 because, you know, there could be predisposing 16 conditions. It could be that the person had other 17 exposures. So I wouldn't say anyone. But in 18 general, you would expect that the timeframe would 19 be longer than three years. 20 Q. You expect the timeframe to be more 21 along the lines of ten to 15 years at least, 22 right? 23 A. That's what you would expect, but you 24 know, it could be that there's something about 25 NDMA that we don't really know about.</p>	<p style="text-align: right;">Page 291</p> <p>1 significant association between bladder cancer and 2 NDMA in valsartan, right? 3 A. No. I don't see bladder cancer. 4 You're looking at table two? 5 Q. No. Table three on page -- 6 A. All right. Sorry. Yeah, right. 7 Right. They didn't -- 8 Q. Let me ask the question, please. 9 Gomm found no statistically 10 significant association between bladder cancer and 11 NDMA in valsartan, correct? 12 A. Yes, correct. 13 Q. No statistically significant 14 association between breast cancer and NDMA in 15 valsartan, correct? 16 A. Correct. 17 Q. No statistically significant 18 association between colorectal cancer and NDMA in 19 valsartan, correct? 20 A. Correct. 21 Q. No statistically significant 22 association between kidney cancer and NDMA in 23 valsartan, correct? 24 A. Correct. 25 Q. No statistically significant</p>
<p style="text-align: right;">Page 290</p> <p>1 Q. It sounds like there's a lot we don't 2 know about NDMA. 3 MR. SLATER: Objection. 4 A. No, I wouldn't say that. I wouldn't 5 say that at all. We know a lot about NDMA. We 6 know a lot about it. 7 Q. Well, it sounds like you didn't hear 8 my question, so let me ask -- 9 MR. SLATER: It wasn't a question -- 10 A. There might be a co-factor involved 11 in these patients. Maybe high blood pressure or 12 hypertension previously unrecognized that shortens 13 the waiting period. 14 Q. Have you ever seen -- 15 A. No, we don't know. 16 Q. Have you ever seen a study suggesting 17 that hypertension shortens the latency period for 18 tumor development? 19 A. No, I haven't seen it. 20 Q. So we were talking about Gomm and I 21 was on page 61 and Gomm provides a table regarding 22 the authors' evaluation of single cancer outcomes. 23 Do you see that? 24 A. Yes. 25 Q. And Gomm found no statistically</p>	<p style="text-align: right;">Page 292</p> <p>1 association between lung cancer and NDMA in 2 valsartan, correct? 3 A. That's correct. But I wonder if 4 these were all nonsmokers. I don't know if that's 5 the case. 6 Q. No statistically significant 7 association between pancreatic cancer and NDMA in 8 valsartan, correct? 9 A. Correct. Well, malignant melanoma. 10 Q. No statistically significant 11 association between prostate cancer and NDMA in 12 valsartan, correct? 13 A. Correct. 14 Q. No statistically significant 15 association between uterine cancer and NDMA in 16 valsartan? 17 A. Right. 18 Q. Do you agree that the metabolism of 19 NDMA and NDEA is the only mechanism by which these 20 substances could possibly cause a mutation? 21 A. Yes. 22 Q. So NDMA and NDEA could circulate in 23 the body and unless and until they become 24 metabolized, they'll just be excreted without 25 causing harm, right?</p>

<p style="text-align: right;">Page 293</p> <p>1 A. Say that again, please.</p> <p>2 Q. Absent -- what I was saying was until</p> <p>3 NDMA and NDEA become metabolized, they would</p> <p>4 simply be excreted from the body without causing</p> <p>5 harm?</p> <p>6 A. That's true, but, in fact, you see</p> <p>7 very little excretion of unchanged NDMA in the</p> <p>8 urine. When it's taken orally, it's metabolized</p> <p>9 very effectively by the liver and other tissues.</p> <p>10 Q. Does most of the metabolism of the</p> <p>11 NDMA occur in the liver?</p> <p>12 A. As far as we know, yes.</p> <p>13 Q. And at this point in time, would you</p> <p>14 say that the scientific community has good data on</p> <p>15 the metabolism of NDMA and NDEA in the human body?</p> <p>16 A. Yes.</p> <p>17 Q. Do you agree then that the primary</p> <p>18 metabolism of NDMA and NDEA takes place through</p> <p>19 the cytochrome P450 enzyme?</p> <p>20 A. Yes.</p> <p>21 Q. And that's in the liver. That's</p> <p>22 where that enzyme is primarily located, right?</p> <p>23 A. No. They're in other tissues also.</p> <p>24 Q. It's not in every organ system of the</p> <p>25 body, is it?</p>	<p style="text-align: right;">Page 295</p> <p>1 in 2021 to evaluate the type of DNA damage caused</p> <p>2 by nitrosamines"?</p> <p>3 A. I don't think I ever made that</p> <p>4 statement, no. We have a lot of data. We have a</p> <p>5 huge amount of data.</p> <p>6 Q. Who is Joseph Guttenplan,</p> <p>7 G-U-T-T-E-N-P-L-A-N?</p> <p>8 A. Guttenplan.</p> <p>9 Q. Sorry for the mispronunciation.</p> <p>10 Who is Joseph Guttenplan?</p> <p>11 A. He's a scientist at New York</p> <p>12 University.</p> <p>13 Q. Is he an expert in the field of</p> <p>14 chemical drug and genetic drug toxicology?</p> <p>15 A. Yes.</p> <p>16 Q. Was Dr. Guttenplan part of the FDA</p> <p>17 workshop that took place in March?</p> <p>18 A. Yes, he was there.</p> <p>19 Q. During that workshop was one of the</p> <p>20 issues that was discussed the body's DNA repair</p> <p>21 mechanisms?</p> <p>22 A. Yes.</p> <p>23 Q. In that workshop, was it discussed</p> <p>24 among the experts and agreed that the small</p> <p>25 amounts of nitrosamines in medication were sub</p>
<p style="text-align: right;">Page 294</p> <p>1 A. Just about.</p> <p>2 Q. Just the enzyme?</p> <p>3 A. Yes. There are different forms in</p> <p>4 different tissues. Not just in the liver. The</p> <p>5 lung, kidney, small intestine, esophagus, oral</p> <p>6 cavity. They all have P450 enzymes. The liver,</p> <p>7 of course, is the main metabolizing organ in the</p> <p>8 body and has a higher P450 content than other</p> <p>9 tissues, but all tissues have P450s. Different</p> <p>10 ones. There are whole books written on it.</p> <p>11 Q. Okay. I'll take your word for it.</p> <p>12 Does the scientific community at this</p> <p>13 point in time have a great deal of valid reliable</p> <p>14 data about the type of DNA damage caused by NDMA</p> <p>15 and NDEA?</p> <p>16 A. Yes.</p> <p>17 Q. Have you ever stated that there are</p> <p>18 ways to look at a DNA adduct formation and how</p> <p>19 much damage comes from nitrosamine exposure but</p> <p>20 right now, in 2021, we don't have that type of</p> <p>21 data?</p> <p>22 A. I'm not sure I understand your</p> <p>23 question.</p> <p>24 Q. My question is simply have you ever</p> <p>25 made the statement that "We do not have the data</p>	<p style="text-align: right;">Page 296</p> <p>1 threshold with respect to the body's DNA repair</p> <p>2 abilities?</p> <p>3 A. May have been discussed, but I don't</p> <p>4 recall that that conclusion was made.</p> <p>5 Q. Did Dr. Guttenplan observe that the</p> <p>6 nitrosamine levels in medicines were so low that</p> <p>7 they were not approaching threshold for enzyme</p> <p>8 saturation? Do you remember that comment or</p> <p>9 observation being made?</p> <p>10 A. For which enzyme? Repair enzymes,</p> <p>11 you mean?</p> <p>12 Q. Yes, sir.</p> <p>13 A. I don't follow what you mean.</p> <p>14 Q. My question was did Dr. Guttenplan</p> <p>15 state at the FDA workshop that the levels of</p> <p>16 nitrosamines in medicines were so low that they</p> <p>17 were not approaching thresholds for enzyme</p> <p>18 saturation in the body?</p> <p>19 A. You're still not clear. First, you</p> <p>20 were talking about DNA repair enzymes and then</p> <p>21 you're talking about nitrosamine metabolizing</p> <p>22 enzymes, so I'm not sure which ones you're</p> <p>23 actually referring to.</p> <p>24 Q. When Dr. Guttenplan used the term</p> <p>25 "sub threshold," what did you understand that to</p>

<p style="text-align: right;">Page 297</p> <p>1 mean?</p> <p>2 A. I believe -- I believe he's talking</p> <p>3 about with respect to the nitrosamine-metabolizing</p> <p>4 enzyme, like 452E1 and others that are in the</p> <p>5 body, that those enzymes are not saturated by the</p> <p>6 kind of exposure that you would get from</p> <p>7 valsartan.</p> <p>8 Q. When those enzymes are not saturated,</p> <p>9 what that means is that our body has the ability</p> <p>10 to deal with those small levels of carcinogens,</p> <p>11 correct?</p> <p>12 A. Deal with them, yes. In dealing with</p> <p>13 them, it creates a DNA damaging agent. That</p> <p>14 metabolism is absolutely required for NDMA to</p> <p>15 cause liver cancer.</p> <p>16 Q. Who is Dr. Richard Adamson?</p> <p>17 A. He's a consultant now. He's a former</p> <p>18 director of the Division of Cancer Etiology at the</p> <p>19 National Cancer Institute, which is the US -- main</p> <p>20 US governing body that does research on cancer.</p> <p>21 Q. Was Dr. Adamson also at the workshop</p> <p>22 in March?</p> <p>23 A. Yes.</p> <p>24 Q. Do you recall Dr. Adamson also</p> <p>25 discussing the issue of the body's DNA repair</p>	<p style="text-align: right;">Page 299</p> <p>1 the body's repair enzymes?</p> <p>2 MR. SLATER: Objection.</p> <p>3 Lack of foundation. Multiple --</p> <p>4 A. It's totally confusing, what you're</p> <p>5 saying. Okay? The low levels would be very</p> <p>6 effectively metabolized by the P450s in the liver</p> <p>7 and other tissues of the body, leading to the</p> <p>8 formation of highly reactive DNA damaging</p> <p>9 intermediates that cause mutations in DNA. Some</p> <p>10 of those may be repaired by a repair enzyme such</p> <p>11 as MGMT and I think what you're saying is that the</p> <p>12 MGMT activity would not be saturated. I think</p> <p>13 that's what you're referring to, but the way</p> <p>14 you're saying is it very confusing. Really</p> <p>15 muddies the water.</p> <p>16 The bottom line is that your body</p> <p>17 definitely has the ability to convert the NDMA in</p> <p>18 valsartan to a DNA methylating agent that's going</p> <p>19 to form O6-methylguanine. I can tell you with</p> <p>20 100% certainty that a person who takes a tablet of</p> <p>21 valsartan that's contaminated with</p> <p>22 dimethylnitrosamine will form a finite amount of</p> <p>23 O6-methylguanine in their DNA. Some of that may</p> <p>24 be repaired. Some of it may lead to mutations.</p> <p>25 Q. My question was at the FDA workshop</p>
<p style="text-align: right;">Page 298</p> <p>1 mechanisms and whether low levels of NDMA or NDEA</p> <p>2 in drug products was expected to present a</p> <p>3 significant risk of harm to the patient</p> <p>4 population?</p> <p>5 A. I don't recall his exact comments,</p> <p>6 but he's certainly an expert. He has done studies</p> <p>7 exposing primates to NDEA.</p> <p>8 Q. Isn't it true that Dr. Adamson stated</p> <p>9 that the low levels of nitrosamines in the drugs</p> <p>10 were so low that he would not expect any long-term</p> <p>11 risk of patient health since there was no</p> <p>12 saturation or competition for activation of the</p> <p>13 body's repair enzymes at those levels?</p> <p>14 A. Are you quoting?</p> <p>15 Q. I'm asking if that's what you heard</p> <p>16 him say.</p> <p>17 A. I don't remember if that's what I</p> <p>18 heard him say. I'm asking you whether you're</p> <p>19 quoting from the transcript. In that case, it's</p> <p>20 true.</p> <p>21 Q. So is that statement correct, that</p> <p>22 low levels of exposure to nitrosamines would not</p> <p>23 be expected to cause long-term harm to the patient</p> <p>24 population because those levels would not be</p> <p>25 expected to saturate or compete for activation of</p>	<p style="text-align: right;">Page 300</p> <p>1 in March, was it the conclusion of the scholars</p> <p>2 that were impaneled by FDA that the levels in this</p> <p>3 case were so low that there was not expected to be</p> <p>4 a significant risk to public health because the</p> <p>5 body's repair mechanisms would allow for or</p> <p>6 prevent the development of mutations?</p> <p>7 A. Yes, that was the conclusion.</p> <p>8 Q. I guess --</p> <p>9 MR. SLATER: Objection.</p> <p>10 A. What?</p> <p>11 Q. I guess then what I'd like to ask you</p> <p>12 is this --</p> <p>13 A. Are you quoting? I mean, were you</p> <p>14 quoting from the report?</p> <p>15 MR. SLATER: Doctor, if you want to</p> <p>16 see the transcripts, you could ask him to</p> <p>17 show it to you.</p> <p>18 Q. I'm just asking you a question.</p> <p>19 A. I'm just asking you whether you're</p> <p>20 quoting from the report or not.</p> <p>21 Q. I asked you if that was a conclusion</p> <p>22 of the panelists.</p> <p>23 A. I don't remember. I mean, you have</p> <p>24 the report right in front of you, so why don't you</p> <p>25 tell me?</p>

<p style="text-align: right;">Page 301</p> <p>1 Q. We know that you've done research on 2 NNN and NNK in your career and we know that both 3 of those are known Class 1 carcinogens in tobacco, 4 right? 5 A. Correct. 6 Q. We know that tobacco also is laced 7 with other carcinogens, not just those two tobacco 8 nitrosamines, right? 9 A. Tobacco smoked, yes. Unburnt tobacco 10 is another story. 11 Q. I've been led to believe -- and I 12 don't know whether it's true or not -- is that 13 tobacco contained over 70 carcinogens. 14 Is that the case? 15 A. Tobacco smoke, yes. 16 Q. I think that you have written that 17 cigarette smoking causes up to 90% of all the lung 18 cancers in the world and is the largest cause of 19 cancer death in the world, yet only ten to 20% of 20 lifetime smokers will get lung cancer? 21 A. Correct. It's no longer the largest 22 cause of cancer in women in the world. That's 23 breast cancer. But everything else you said is 24 correct. 25 Q. All right.</p>	<p style="text-align: right;">Page 303</p> <p>1 of cancer in the US population is? 2 A. What do you mean by background rate? 3 Q. How many people will get cancer in 4 one form or another in their lifetime? 5 A. Yes. I know that number, but I'm 6 afraid I can't quote it off the top of my head. 7 But that number is certainly available. 8 Q. Okay. 9 Do you know what the background rate 10 of cancer among Americans over the age of 50 who 11 suffer from hypertension might be? 12 A. Not offhand. 13 Q. Are you able -- 14 A. I don't know what you mean by 15 background. 16 Q. Maybe -- 17 A. What does background mean? 18 Q. Maybe it's just my poor language. 19 I'm just trying to tell, you know, 20 how many -- what percentage of Americans over the 21 age of 50 who have hypertension will develop 22 cancer? 23 A. I can't answer that offhand. It's 24 definitely available. 25 Q. I'm only asking --</p>
<p style="text-align: right;">Page 302</p> <p>1 We talked earlier about the Gushgari 2 paper that told us that the estimate is that 3 smoking leads to the injection of 25,000 nanograms 4 of nitrosamines per day. 5 Do you remember that? 6 A. Yes. 7 Q. And I assume that doesn't need -- 8 that's not even taking into account then the other 9 carcinogens contained in tobacco smoke, right? 10 A. Correct. 11 Q. So if only ten to 20% of individuals 12 exposed to 25,000 nanograms a day of nitrosamines 13 plus other carcinogens acquire lung cancer after a 14 lifetime of smoking, do you have any estimate or 15 are you capable of providing an estimate as to the 16 percentage of valsartan users that you would 17 expect to develop cancer from a less-than-lifetime 18 exposure to nitrosamines? 19 A. I'm not capable of making that 20 calculation, but presumably the risk would be less 21 than from smoking. 22 Q. Do you know what the -- 23 A. I cannot make that calculation. 24 Q. Okay. Fair enough. 25 Do you know what the background rate</p>	<p style="text-align: right;">Page 304</p> <p>1 A. Definitely available. 2 Q. I understand. I'm only asking -- 3 A. I can't keep all those figures in my 4 brain. 5 Q. I'm just asking what you know. If 6 you don't know, just tell me you don't know. 7 Do you intend to present this court 8 with any statistical or epidemiological evidence 9 to say that there will be a statistically 10 significant increased rate of cancer above the 11 background rate simply because of a 12 less-than-lifetime increase in the intake of NDMA 13 when all of the individual plaintiffs have already 14 been exposed to nitrosamines exogenously every day 15 of their life? 16 MR. SLATER: Objection. 17 You can answer. 18 A. First of all, your question doesn't 19 make a lot of sense the way -- 20 Q. Well, which part doesn't -- 21 A. The way that all the people have been 22 exposed to nitrosamines every day of their life. 23 That's incredibly nonquantitative. I mean, I 24 could never agree with a statement like that. 25 In any case, I'm not intending to</p>

<p style="text-align: right;">Page 305</p> <p>1 make any numerical estimates because that's not 2 what I do. That's for the risk assessors to do. 3 Q. That's fine. This is what I'm just 4 trying to find out. Let's just assume 5 hypothetically that those readily-available 6 statistics you talk about tell us that 30% of 7 people over the age of 50 who have hypertension 8 will develop cancer in one form or another. 9 Okay? 10 A. Okay. 11 Q. And you just accept that number -- 12 A. Okay. 13 Q. -- for the purpose of my question. 14 A. Right. 15 Q. What I'm trying to figure out is are 16 you going to offer an opinion that that population 17 subgroup is at some statistical increased risk of 18 cancer just because they received a 19 less-than-lifetime increase in the intake of NDEA 20 or NDMA for some period of time? 21 A. Yes. I would be comfortable with 22 offering an opinion, but not necessarily making a 23 calculation. 24 Q. Well, that was my question. 25 What is the -- what is that increased</p>	<p style="text-align: right;">Page 307</p> <p>1 anything new to ask, but please don't come in 2 and make me start objecting and have a back 3 and forth. I would appreciate that because 4 it's been a long day and I have some 5 questions to follow up on from Mr. 6 Trischler's lengthy questioning. 7 MR. FOWLER: Good afternoon, 8 Dr. Hecht. It's Steven Fowler with Greenberg 9 Traurig. 10 I believe the remaining defendants 11 have an hour and a half or so of questions. 12 I've got quite a bit of questions. I assure 13 you it's not my intent to ask any questions 14 that Dr. Hecht has answered, but I do have 15 questions and I'm just -- in fairness, I 16 think it's about an hour and a half or so -- 17 MR. SLATER: Go ahead. Start your 18 questioning. I've heard that before. 19 Let's get going and we'll go question 20 by question and see if it's new questions 21 because it's impossible for me to imagine -- 22 unless you guys are just going to walk the 23 dog and come up with things to ask about that 24 are hyper specific to a specific manufacturer 25 just to ask questions, I feel like this has</p>
<p style="text-align: right;">Page 306</p> <p>1 risk? Can you calculate it or estimate it? 2 A. No, I can't. I can't do that. 3 That's not what I do. 4 Q. That would be the same thing for -- I 5 think I -- 6 A. For both. 7 Q. That would be the case for both 8 NDMA and NDEA -- 9 A. That's for the risk assessor to do. 10 Like EMA and any others. 11 MR. TRISCHLER: I think I'm ready to 12 pass the witness. 13 I think the information that I 14 received, Adam, is that there are others who 15 have -- a few others that have questions, 16 maybe one or two on the side, but I'll let 17 them speak for themselves and I don't know if 18 that's been updated since I finished. So -- 19 but I think -- 20 MR. SLATER: Whoever it is needs to 21 identify themselves and I'm going to object 22 to and expect that there will not be any 23 questioning that's going to go into the areas 24 that Mr. Trischler covered. 25 It's hard for me to imagine there is</p>	<p style="text-align: right;">Page 308</p> <p>1 been a thorough deposition and we should be 2 able to turn it over to me soon. 3 So go ahead. Start asking your 4 questions, please. 5 MR. FOWLER: I will and I'll 6 appreciate if you simply just object to 7 form and -- 8 MR. SLATER: I don't need a 9 coaching -- 10 MR. FOWLER: -- launching into the 11 diatribes I've been hearing all day, so just 12 object to form and I'll ask my questions. 13 MR. SLATER: Okay. Now that you 14 you're done talking I'll respond. 15 Please don't coach me. Please don't 16 tell me what to do -- 17 MR. FOWLER: Same here. 18 MR. SLATER: -- but please realize 19 that duplicative questions, you'll need to 20 move from question to question. 21 You may proceed. 22 MR. FOWLER: What I'd like to do 23 first -- good afternoon, Dr. Hecht. My name 24 is Steve Fowler on behalf of the Teva 25 defendants.</p>

<p style="text-align: right;">Page 309</p> <p>1 What I'd like to do first is actually 2 mark as the next exhibit your Notice of 3 Deposition today. I don't think that that's 4 been marked. 5 Can we get that marked -- 6 MR. SLATER: You're going to need to 7 do that yourself, sir. You're going to 8 have to have someone put it up. 9 MR. FOWLER: Adam, I'm not talking to 10 you. 11 Steve, are you able to share the 12 screen? We have three Steves on the line. 13 THE VIDEOGRAPHER: Do you have 14 somebody else who is going to be displaying? 15 MR. FOWLER: The exhibit was just 16 introduced and it can be displayed by the 17 concierge as I understand. 18 THE VIDEOGRAPHER: As far as the 19 record, it will be Exhibit 23. 20 (Whereupon, Exhibit 23 was marked for 21 identification.) 22 MR. FOWLER: Is it going to be 23 displayed or am I going to -- 24 MR. SLATER: It's on the screen. 25</p>	<p style="text-align: right;">Page 311</p> <p>1 Q. Do you maintain any -- setting aside 2 this litigation, Doctor, do you maintain a file on 3 nitrosamine as being an area of your research 4 we've heard about today? 5 A. Yes, I do. Yes. 6 Q. And do you maintain that with paper 7 copies of journal articles you may have printed 8 over the years? 9 A. Yes. I have several file cabinets, 10 but, you know, in the last, I don't know, eight 11 years or so, everything is online. 12 Q. Is your file on nitrosamines 13 organized at all by particular nitrosamines such 14 as NDMA or NDEA? 15 A. No. 16 Q. When you were asked to participate in 17 the FDA panel, did you undertake any preparation 18 for that panel? Did you undertake any research 19 before you appeared? 20 A. No. 21 Q. With you today, Doctor, do you have 22 any -- let me ask you this: I've seen you pick up 23 the red book a couple times. 24 What else do you have in your space 25 there at your office? Can you hold it up? Do you</p>
<p style="text-align: right;">Page 310</p> <p>1 EXAMINATION BY 2 MR. FOWLER: 3 Q. Doctor, have you seen this document 4 before? 5 A. No. 6 Q. I would submit this is the notice for 7 you today and if we can go to page three of the 8 notice, you'll see that we've asked for certain 9 items to be brought with you and that would 10 include any sort of files or records that you have 11 with regard to this subject matter. 12 And Dr. Hecht, I heard today you've 13 spent much of your career on nitrosamines and my 14 question to you is do you have a file that you've 15 maintained on nitrosamines and the risk of 16 carcinogenicity? 17 A. A file on risk of carcinogenicity in 18 humans? In animals? 19 Q. Let me break it down. 20 Do you have a file on nitrosamines, 21 Doctor? 22 A. A file? Everything is summarized in 23 my publications. I mean, I do not have all of the 24 original records from the research that we've 25 done. I have files and --</p>	<p style="text-align: right;">Page 312</p> <p>1 have binders? What do you have, sir? 2 A. In my office? 3 MR. SLATER: Dr. Hecht, one second. 4 This was covered extensively earlier. 5 MR. FOWLER: It wasn't. I've seen 6 him picking up things and looking at things. 7 I just want to know what else he's got. 8 THE WITNESS: You want me to answer 9 him? 10 MR. SLATER: Yeah, go ahead, answer 11 him. 12 We've moving quickly towards 13 concluding his questioning if this is -- 14 A. I have binders that have the 15 publications and the other data that was mentioned 16 in the written document and I have some of my 17 books that I refer to, including, you know, the 18 IARC 1978 valuation. I have all of the IARC 19 monographs up until about year 2000 or maybe a 20 little later. They're not all here in my office 21 anyhow. 22 Q. Thank you, sir. 23 A. Does that answer your question? 24 Q. I believe so, sir. Thank you. 25 Doctor, when evaluating the issue</p>

<p style="text-align: right;">Page 313</p> <p>1 before you, which I think we've acknowledged is</p> <p>2 whether the level of NDMA and NDEA found in the</p> <p>3 valsartan products increases the risk of</p> <p>4 carcinogenicity, did you apply a specific level</p> <p>5 of -- let's start with NDMA -- in your analysis as</p> <p>6 it pertains to the valsartan products?</p> <p>7 MR. SLATER: Objection.</p> <p>8 You can answer.</p> <p>9 A. No. I mean, I did not do a risk</p> <p>10 assessment.</p> <p>11 Q. Am I correct you were --</p> <p>12 A. That was done by others.</p> <p>13 Q. You were attempting to evaluate</p> <p>14 whether or not the levels of NDMA and NDEA in the</p> <p>15 valsartan tablets poses an increased risk. Wasn't</p> <p>16 that what the question you were answering? I</p> <p>17 thought we heard that earlier.</p> <p>18 MR. SLATER: Objection.</p> <p>19 Asked and answered.</p> <p>20 You can answer.</p> <p>21 A. I don't know what you mean by</p> <p>22 increased risk. Sure, there's an increase in</p> <p>23 risk. No doubt about it. It shouldn't be there.</p> <p>24 The amount should be zero, but I didn't -- I did</p> <p>25 not do the formal risk assessment. Those were</p>	<p style="text-align: right;">Page 315</p> <p>1 consumed and my question is simply this --</p> <p>2 MR. SLATER: You know what, counsel?</p> <p>3 Before you ask a question, we're taking a</p> <p>4 break.</p> <p>5 MR. FOWLER: Don't talk over me.</p> <p>6 MR. SLATER: We're taking a break.</p> <p>7 We've been going over an hour again. It's</p> <p>8 5:30 on the east coast, it's 4:30 -- the</p> <p>9 doctor has been going for now</p> <p>10 eight-and-a-half hours, so we're going to</p> <p>11 take a break.</p> <p>12 MR. FOWLER: I was in the middle of a</p> <p>13 question --</p> <p>14 MR. SLATER: I stopped you before you</p> <p>15 asked it, you talked over me. We're going to</p> <p>16 take a break for ten minutes.</p> <p>17 MR. FOWLER: Okay.</p> <p>18 Thank you, Doctor. We will take a</p> <p>19 break.</p> <p>20 THE VIDEOGRAPHER: Time is 5:34.</p> <p>21 This concludes media five.</p> <p>22 (Recess taken)</p> <p>23 THE VIDEOGRAPHER: The time is now</p> <p>24 5:49.</p> <p>25 This begins media six.</p>
<p style="text-align: right;">Page 314</p> <p>1 done by FDA and EMA, among others.</p> <p>2 Q. What level --</p> <p>3 A. And I don't do it. That's not what I</p> <p>4 do.</p> <p>5 Q. I understand, Doctor.</p> <p>6 What level of NDMA are you operating</p> <p>7 from when evaluating the valsartan?</p> <p>8 A. Zero.</p> <p>9 Q. Doctor, you understand FDA has</p> <p>10 found --</p> <p>11 A. It should be zero.</p> <p>12 Q. Doctor, that's a liability --</p> <p>13 A. It should be zero.</p> <p>14 Q. This can take a while.</p> <p>15 A. The amounts that have been found in</p> <p>16 the API from ZHP ranged from about ten to 120</p> <p>17 parts per million, I believe.</p> <p>18 Q. Do you believe that the levels in the</p> <p>19 API is the same as the levels of NDMA in finished</p> <p>20 dose valsartan products?</p> <p>21 A. No. No. It would be -- it would be</p> <p>22 higher than the API for finished products.</p> <p>23 Q. Right.</p> <p>24 So we're only here today about the</p> <p>25 finished dose products that plaintiffs allegedly</p>	<p style="text-align: right;">Page 316</p> <p>1 You may proceed.</p> <p>2 Q. Doctor, what I was trying to get at</p> <p>3 earlier is simply this question: Do you think and</p> <p>4 agree that it's reasonable for those scientists</p> <p>5 who are evaluating the risk, if any, from the</p> <p>6 levels of NDMA and NDEA in the valsartan to use</p> <p>7 the geometric mean value of all of the levels FDA</p> <p>8 measured in a particular dose of valsartan?</p> <p>9 MR. SLATER: Objection.</p> <p>10 I don't understand.</p> <p>11 THE WITNESS: Do you want me to</p> <p>12 answer that now?</p> <p>13 MR. SLATER: If you can --</p> <p>14 A. Were you going to reply to his</p> <p>15 objection first?</p> <p>16 Q. I have no reason to.</p> <p>17 Go ahead, Doctor, if you do</p> <p>18 understand the question.</p> <p>19 A. Could you repeat it again please?</p> <p>20 Q. Yes, sir.</p> <p>21 Do you agree it makes sense to take</p> <p>22 an average number, a geometric mean of all of the</p> <p>23 various manufacturers levels of NDMA measured by</p> <p>24 FDA in, let's say, the 320 milligram dose of</p> <p>25 valsartan when evaluating what, if any, risk</p>

<p style="text-align: right;">Page 317</p> <p>1 exists from that level of NDMA?</p> <p>2 Do you understand that?</p> <p>3 A. Yeah. You want to take the geometric</p> <p>4 mean from all of the manufacturers. I'm not sure</p> <p>5 that really makes sense because the different</p> <p>6 manufacturers may have different amounts.</p> <p>7 Q. For example, you would not expect any</p> <p>8 single patient to have taken the highest level of</p> <p>9 NDMA detected in the 320 milligram valsartan for</p> <p>10 the period at issue, would you?</p> <p>11 MR. SLATER: Objection.</p> <p>12 A. I wouldn't know. I have no idea.</p> <p>13 Q. So do you think it's unreasonable to</p> <p>14 take an average number of all of the manufacturers</p> <p>15 of the affected valsartan when evaluating the</p> <p>16 risk?</p> <p>17 MR. SLATER: Objection.</p> <p>18 You can answer again.</p> <p>19 A. I really don't know. I mean, an</p> <p>20 average would be the place to start, I suppose.</p> <p>21 Q. Okay.</p> <p>22 A. You know, one would have to be</p> <p>23 mindful also of the high doses because the high</p> <p>24 doses are where you more likely see an effect. So</p> <p>25 it might make sense to evaluate the high doses</p>	<p style="text-align: right;">Page 319</p> <p>1 You can answer.</p> <p>2 A. Come back to it again. I mean, I</p> <p>3 didn't do a formal risk assessment. That's not</p> <p>4 what I do. So --</p> <p>5 Q. I understand, Doctor.</p> <p>6 A. -- I don't really know what you're</p> <p>7 driving at with this question. I already told you</p> <p>8 I don't do these calculations. EMA did</p> <p>9 calculations, FDA did calculations. Their results</p> <p>10 are, I think, all documented.</p> <p>11 Q. In your research --</p> <p>12 A. I don't really see what you're</p> <p>13 asking -- why you're asking me. I mean, ask the</p> <p>14 person at EMA who did the calculations.</p> <p>15 Q. Thank you, Doctor.</p> <p>16 When you've done your research on</p> <p>17 other nitrosamines and in tobacco, like the NNN</p> <p>18 and NNK, do you ever evaluate the level of NNN or</p> <p>19 NNK in writing your papers or forming your</p> <p>20 conclusions on those studies?</p> <p>21 A. Yes, we do.</p> <p>22 Q. The levels are important, correct?</p> <p>23 A. Yes, they are.</p> <p>24 Q. I think we started the day with dose</p> <p>25 and duration are a key to any evaluation.</p>
<p style="text-align: right;">Page 318</p> <p>1 first, you know, above, let's say, the 80th</p> <p>2 percentile, something like that. And you know, if</p> <p>3 you didn't find an effect there, then you could</p> <p>4 probably safely conclude that there would be no</p> <p>5 effect to the lower doses.</p> <p>6 So I'm not sure that the geometric</p> <p>7 mean is necessarily the way to go about this. As</p> <p>8 I mentioned, I'm not the risk assessor, so you</p> <p>9 really -- you're bringing me into an area that's</p> <p>10 not my area of expertise.</p> <p>11 Q. Yes, sir, thank you.</p> <p>12 And it follows from that that you</p> <p>13 made no attempt to evaluate the specific level of</p> <p>14 NDMA from any of the manufacturers' valsartan</p> <p>15 tablets that FDA measured. You didn't consider</p> <p>16 any of those specific levels in forming the</p> <p>17 opinions we see in your report; is that correct?</p> <p>18 MR. SLATER: Objection.</p> <p>19 A. I didn't do calculations, no.</p> <p>20 Q. You didn't rely on any of the</p> <p>21 specific numbers that FDA measured in any of the</p> <p>22 valsartan in forming the opinions contained in</p> <p>23 your report, correct?</p> <p>24 MR. SLATER: Objection.</p> <p>25 Lack of foundation.</p>	<p style="text-align: right;">Page 320</p> <p>1 Do you agree with that?</p> <p>2 A. Yes.</p> <p>3 Q. Doctor, forgive me, I'm going to --</p> <p>4 in an effort to be efficient, I'm going to jump</p> <p>5 around a little bit, so forgive me if they're</p> <p>6 disjointed and if you don't follow me, please let</p> <p>7 me know.</p> <p>8 Exhibit 1 is your report. If you</p> <p>9 could please -- I'll direct your attention to page</p> <p>10 eight.</p> <p>11 A. Okay.</p> <p>12 Q. The last full paragraph that begins</p> <p>13 "The pharmacokinetics ..." -- are you with me,</p> <p>14 sir?</p> <p>15 A. Yes.</p> <p>16 Q. You state in the third line</p> <p>17 "Consistently, these studies have demonstrated</p> <p>18 high systemic clearance and high oral</p> <p>19 bioavailability of NDMA."</p> <p>20 Do you see that?</p> <p>21 A. Yes.</p> <p>22 Q. The support for that statement is</p> <p>23 contained in part of that Dr. Gombar beagle study</p> <p>24 that we looked at; is that correct?</p> <p>25 A. Yeah.</p>

<p style="text-align: right;">Page 321</p> <p>1 Q. And if we could please look again at 2 Exhibit -- at Exhibit 8, the beagle study -- 3 THE VIDEOGRAPHER: Would you like 4 that up on the screen, Counsel? 5 MR. FOWLER: Just pause on that. 6 I may be able to move quicker. 7 Q. Doctor, let me ask you do you have 8 any understanding of the -- any differences 9 between the metabolism of the capacity of a beagle 10 to metabolize NDMA with the CYP2E1 enzyme compared 11 to humans? Do you have any understanding of that? 12 A. I don't know if 2E1 has actually been 13 identified in beagles. I'm not sure of that. 14 Q. If beagles -- 15 A. I think Gombar's conclusions were 16 actually a little bit different. I think, if I 17 remember correctly, the beagle studies came to a 18 slightly different conclusion regarding the 19 clearance of NDMA by the liver than the other 20 studies. 21 Q. Doctor, if a beagle only has a 22 quarter of the metabolic capacity for NDMA as 23 compared to a human, would you agree that dogs 24 would have less capacity to clear any oral dose of 25 NDMA?</p>	<p style="text-align: right;">Page 323</p> <p>1 to enter the liver through the mesentery vessels, 2 is it? 3 A. Well, the distribution will be 4 different, but ultimately, it'll be metabolized. 5 Q. Would it be metabolized -- it would 6 reach organs that orally ingested via a tablet 7 would never reach, correct, Doctor? 8 A. I don't know about never, but ... 9 Q. Okay. 10 Are you intending to offer an opinion 11 as kind of set forth on Exhibit 8 that in humans 12 that NDMA has a high systemic clearance and high 13 oral bioavailability? 14 A. That's what the literature indicates. 15 Q. Is there any literature other than 16 the Gombar articles on pharmacokinetics that 17 you're relying on, sir? 18 A. It's been done in multiple different 19 species pharmacokinetic studies. There's a lot of 20 them. There's a lot of data -- 21 Q. Yes, sir. 22 A. -- as stated in the report. 23 Q. There was a third article in the 24 Gombar series of pharmacokinetic testing that you 25 had in your materials.</p>
<p style="text-align: right;">Page 322</p> <p>1 A. Sure. I mean, if they have less -- 2 if they have -- if they have less of the P450 3 metabolizing enzymes in their liver and other 4 tissue than humans, then they would have less 5 capacity to clear the dose of the metabolism. 6 Q. Do you recall the manner of exposure 7 in that beagle study? Do you recall whether it 8 was by IV? 9 A. I think it was IV. 10 Q. And you agree, Doctor, with regard to 11 metabolism, the route of exposure is essential to 12 understanding the route of metabolism, correct? 13 A. Right. 14 Q. And the route of exposure makes a 15 difference in the route of metabolism; true? 16 A. It can effect it, sure. 17 Q. So the metabolism that you would 18 expect from an IV or an IP administration of a 19 compound like NDMA, you would expect that to show 20 different results than through an ingestion of an 21 oral tablet containing some level of NDMA, 22 correct? 23 A. Possibly. 24 Q. That's a medical fact, isn't it, 25 Doctor, that if it's injected IP, it's not going</p>	<p style="text-align: right;">Page 324</p> <p>1 Correct, Dr. Hecht? 2 A. Say it again. 3 Q. There's a third article in Dr. 4 Gombar's series, if you will, on the 5 pharmacokinetics of N-nitrosodimethylamine. 6 Right? 7 A. Okay. 8 MR. FOWLER: I'd like to mark the 9 next exhibit. 10 This is the Gombar article, 1990, 11 "Interspecies scaling of pharmacokinetics of 12 then nitrosodimethylamine." 13 Bear with me, Doctor. 14 That should pop up. 15 THE VIDEOGRAPHER: I'm looking for 16 it. You didn't upload it by any chance, did 17 you? 18 MR. FOWLER: I just uploaded it as 19 Exhibit 24. 20 THE VIDEOGRAPHER: Excellent. Give 21 me one moment to download it. I'm not seeing 22 it on our Novak share file. 23 Did you put it on the Veritext 24 Exhibit Share by any chance? 25 MR. FOWLER: Yes.</p>

<p style="text-align: right;">Page 325</p> <p>1 (Whereupon, Exhibit 24 was marked for 2 identification.) 3 Q. Doctor, do you happen to have a hard 4 copy of this in your materials? 5 A. No. 6 Q. We'll do it on the screen. That's 7 fine, sir. Okay. Thank you. 8 If we can please turn to the third 9 page where it begins the discussion -- it's 10 article page 4368. There you go. 11 The very first sentence of that 12 discussion, sir, states "The role that the 13 pharmacokinetics of a carcinogen plays its impact, 14 both qualitatively, i.e. target organ, and 15 quantitatively, i.e. risk assessment, has not been 16 adequately determined for most compounds assumed 17 or suspected to be human carcinogens." 18 Did I read that correctly there, 19 Doctor? 20 A. Yes. 21 Q. Do you agree that for NDMA and NDEA 22 there has been sufficient study done to adequately 23 understand the metabolism of those two 24 nitrosamines? 25 A. There's pretty extensive data, yes.</p>	<p style="text-align: right;">Page 327</p> <p>1 generally in the literature that the main target 2 tissue of NDMA in animals -- laboratory animals -- 3 is the liver and it's not all by oral 4 administration. 5 Q. Doctor, if I use the term "downstream 6 organs" -- 7 A. But there are exceptions. 8 Q. Thank you. I'm sorry. I didn't mean 9 to step on your response. 10 If I use the term "downstream organs 11 to deliver," do you understand what I mean? 12 A. Yes. 13 Q. Okay. 14 Are you aware of any study that was 15 performed on animals using oral ingestion via a 16 tablet -- not drinking water -- via oral ingestion 17 that demonstrated any cancers outside the liver in 18 any oral ingestion studies? 19 A. Of a tablet? 20 Q. Or they have -- and I can't remember 21 the name of the tool where they just put it right 22 down the gullet, but not drinking water is my 23 point, Doctor. 24 A. Yes. Oral intubation. 25 Q. Thank you, sir.</p>
<p style="text-align: right;">Page 326</p> <p>1 Q. Yes, sir. 2 A. I agree that it's pretty well 3 understood. 4 Q. Okay. 5 A. There's always questions remaining. 6 Q. You'll see at the bottom of that that 7 it says "The root of administration can alter the 8 organospecificity as can" -- and it flips to the 9 next page -- "as can manipulation of the clearance 10 with inducers or inhibitors of metabolism." 11 Do you see that, sir? 12 A. Yes. 13 Q. So do you agree with that, that the 14 route of administration can affect the 15 organospecificity of where perhaps NDMA may land? 16 A. I agree with it, but if I'm not 17 mistaken, most studies of NDMA in animals 18 carcinogenicity studies independent of the root of 19 administration show mainly liver cancer. 20 Q. Doctor, did you evaluate the animal 21 studies with an eye towards the route of 22 administration to assess those which best can be 23 analogized to the oral administration through a 24 tablet? Did you make that -- 25 A. No, not specifically, but I know</p>	<p style="text-align: right;">Page 328</p> <p>1 Are you aware of any study that 2 demonstrates at low doses that NDMA has caused any 3 downstream cancer from the liver? 4 MR. SLATER: Objection. 5 You can answer. 6 A. Sure. It causes kidney cancer when 7 the doses exceed a certain level that aren't 8 metabolized by the liver when it's given orally, 9 the doses are too high -- or not too high -- but 10 higher doses will get kidney cancer. 11 Q. Yes, Doctor. 12 Do you agree that NDMA and NDEA are 13 subject to first pass metabolism? 14 A. Yes. 15 Q. Have you made any attempt to 16 determine what the saturation level is for the 17 liver's capacity to handle first pass metabolism 18 NDMA? 19 Do you understand that question? 20 A. In what species? 21 Q. Human, sir. 22 A. Have I made any attempt? No. 23 Q. Have you made any attempt using any 24 of the animal data to understand at what level the 25 liver's ability to fully metabolize and excrete</p>

<p style="text-align: right;">Page 329</p> <p>1 the NDMA is exceeded?</p> <p>2 A. That data is in the literature.</p> <p>3 There's plenty of data on that --</p> <p>4 Q. Did you make any --</p> <p>5 A. -- from the pharmacokinetic studies</p> <p>6 and even from the early studies of Magee and Swan</p> <p>7 that when the metabolic capacity of the liver is</p> <p>8 exceeded in an oral dose, then kidney tumors start</p> <p>9 to appear and there's plenty of data on that. Not</p> <p>10 only tumors, but DNA adduct studies and metabolism</p> <p>11 studies. There's a lot of data regarding the</p> <p>12 first pass clearance of NDMA given orally, a lot</p> <p>13 of data. We understand that really very well.</p> <p>14 Q. So it follows, Doctor, that you would</p> <p>15 understand and agree with the point that NDMA will</p> <p>16 not escape the liver unless the level is at such a</p> <p>17 point that it exceeds the liver's capacity to</p> <p>18 metabolize it, correct?</p> <p>19 A. That's what the -- that's what all</p> <p>20 the data indicates. That's correct.</p> <p>21 Q. I'm also correct that sitting here</p> <p>22 today, you are offering no opinion as to what that</p> <p>23 level of NDMA is, correct?</p> <p>24 A. In humans?</p> <p>25 Q. Sir, yes.</p>	<p style="text-align: right;">Page 331</p> <p>1 A. -- and paid much less attention to.</p> <p>2 Q. I'm sorry.</p> <p>3 A. Much less attention has been paid to</p> <p>4 the formaldehyde which cannot only damage DNA, but</p> <p>5 can cross link DNA.</p> <p>6 Q. Yes, sir.</p> <p>7 You are aware, of course, that</p> <p>8 formaldehyde is endogenously produced, correct?</p> <p>9 A. Yes.</p> <p>10 Q. It would be impossible for you or any</p> <p>11 other scientist to distinguish between</p> <p>12 endogenously-induced formaldehyde DNA damage from</p> <p>13 formaldehyde DNA damage as a result of NDMA</p> <p>14 metabolism, correct?</p> <p>15 A. No. Incorrect.</p> <p>16 Q. You can spot the difference between</p> <p>17 an endogenous formaldehyde and an NDMA</p> <p>18 formaldehyde, sir?</p> <p>19 A. Yes.</p> <p>20 Q. And how do you do that?</p> <p>21 A. Well, I would have to have a label in</p> <p>22 the NDMA that people took into their bodies and</p> <p>23 then the formaldehyde that's released would be</p> <p>24 labeled and I could determine how much came from</p> <p>25 NDMA.</p>
<p style="text-align: right;">Page 330</p> <p>1 A. I'm not.</p> <p>2 Q. In particular, in this case, you're</p> <p>3 not offering an opinion that the levels of NDMA</p> <p>4 and NDEA that were detected in the valsartan at</p> <p>5 issue were such that they would exceed the</p> <p>6 metabolic capacity of the liver, correct, sir?</p> <p>7 A. I doubt that they would. I believe</p> <p>8 that they would be metabolized in the liver.</p> <p>9 That's why it was interesting to see that the</p> <p>10 study from Germany, the insurance study, showed</p> <p>11 liver cancer. But we already discussed that.</p> <p>12 Q. And I didn't ask that part of the</p> <p>13 question, sir.</p> <p>14 A. No, you did not.</p> <p>15 Q. Thank you.</p> <p>16 Doctor, do you agree that once NDMA</p> <p>17 is metabolized by the -- the PY450E1 enzyme that</p> <p>18 that metabolite is very reactive?</p> <p>19 Do you agree with that statement?</p> <p>20 A. One of them is, the methane</p> <p>21 diazohydroxide that everybody concentrates on</p> <p>22 because that's what damages DNA, but there's</p> <p>23 another metabolite that's formed and it's</p> <p>24 formaldehyde, which is also a carcinogen --</p> <p>25 Q. Yes, sir, and --</p>	<p style="text-align: right;">Page 332</p> <p>1 Q. To your knowledge, has that study</p> <p>2 been done?</p> <p>3 A. No.</p> <p>4 Q. Based on --</p> <p>5 A. In humans, it has not.</p> <p>6 Q. Has it been done anywhere that you</p> <p>7 can point to, Doctor?</p> <p>8 A. I don't think it's been done in</p> <p>9 animals either, but, I mean, it could be done in</p> <p>10 animals. We have looked at DNA damage from the</p> <p>11 formaldehyde produced in NDMA metabolism. We did</p> <p>12 that study. But of course in rats, you can just</p> <p>13 give NDMA and we compare to treat it with a</p> <p>14 control. The other way to do is it label NDMA.</p> <p>15 Q. Okay.</p> <p>16 Well, thank you for that.</p> <p>17 But to be clear, the state of the</p> <p>18 science today, you nor anyone else can distinguish</p> <p>19 between endogenously formed formaldehyde DNA</p> <p>20 adduct and an adduct formed as a result of</p> <p>21 formaldehyde from the metabolism of NDMA; isn't</p> <p>22 that correct?</p> <p>23 A. It hasn't been done, but it can be</p> <p>24 done. We're going to do it.</p> <p>25 Q. A lot of projects coming out of this</p>

<p style="text-align: right;">Page 333</p> <p>1 deposition, I see.</p> <p>2 Doctor, you would agree that the NDMA</p> <p>3 once metabolized -- and you've agreed it's</p> <p>4 reactive -- it's going to attach, if you will,</p> <p>5 invade the first cell that it can get into that's</p> <p>6 close by, correct?</p> <p>7 A. The metabolite or the parent NDMA?</p> <p>8 Q. The metabolite. We're talking about</p> <p>9 the mutation that results. It's the --</p> <p>10 A. The metabolite, other than</p> <p>11 formaldehyde, methane diazohydroxide is very short</p> <p>12 lived, so that's going to hit almost where it's</p> <p>13 formed.</p> <p>14 Q. Doctor, you would agree that</p> <p>15 approximately 95% of our DNA is "junk DNA," isn't</p> <p>16 it, sir?</p> <p>17 MR. SLATER: Objection.</p> <p>18 You can answer.</p> <p>19 A. I don't know.</p> <p>20 Q. Let me ask it this way: You agree</p> <p>21 that it is approximately only 5% of DNA is coding</p> <p>22 DNA.</p> <p>23 Are you familiar with that term?</p> <p>24 A. Yes.</p> <p>25 Q. And you agree that only if coding DNA</p>	<p style="text-align: right;">Page 335</p> <p>1 A. Yes.</p> <p>2 MR. SLATER: Objection.</p> <p>3 MR. FOWLER: I wasn't quite done with</p> <p>4 that Gombar article. If we could put up what</p> <p>5 was 24, I want to look further at 4369. I'll</p> <p>6 let you know when to take that down. I've</p> <p>7 got a few questions, please.</p> <p>8 THE VIDEOGRAPHER: What do you mean</p> <p>9 by 2369? Sorry.</p> <p>10 MR. FOWLER: 4369 is the page.</p> <p>11 THE VIDEOGRAPHER: I'm sorry.</p> <p>12 I thought you said 20.</p> <p>13 MR. FOWLER: I probably did.</p> <p>14 BY MR. FOWLER:</p> <p>15 Q. Okay.</p> <p>16 You see the first full paragraph</p> <p>17 begins "We have attempted ..."? </p> <p>18 A. Yeah, barely.</p> <p>19 Q. Yes, sir. There it goes.</p> <p>20 MR. SLATER: Can we blow that up,</p> <p>21 please?</p> <p>22 MR. FOWLER: I think it's blown up.</p> <p>23 Q. Doctor, it states "It is well</p> <p>24 established that NDMA must be metabolized to the</p> <p>25 ultimate methylating species to exert its toxic</p>
<p style="text-align: right;">Page 334</p> <p>1 is mutated that goes on checked, that's the only</p> <p>2 DNA that could result in a malignant</p> <p>3 transformation; agreed?</p> <p>4 A. That's the theory, yes.</p> <p>5 Q. If the mutated NMDA -- let me strike</p> <p>6 that.</p> <p>7 If the metabolized NMDA [sic] reacts</p> <p>8 quickly to a cell nearby and it's junk DNA, it's</p> <p>9 not going to have any ill health effects</p> <p>10 regardless.</p> <p>11 Correct, sir?</p> <p>12 MR. SLATER: Objection.</p> <p>13 You can answer.</p> <p>14 A. I don't know.</p> <p>15 Q. Okay.</p> <p>16 Because you're not a genotoxic</p> <p>17 impurities expert, correct?</p> <p>18 A. Well, I'm not a microbiologist, if</p> <p>19 that's what you're asking.</p> <p>20 Q. You are not a genetic --</p> <p>21 A. I don't know whether an effect on</p> <p>22 so-called junk DNA is necessarily innocuous.</p> <p>23 Q. Yes, sir.</p> <p>24 Can we agree you're not a DNA repair</p> <p>25 expert?</p>	<p style="text-align: right;">Page 336</p> <p>1 effect."</p> <p>2 Correct?</p> <p>3 A. Probably to assert its carcinogen.</p> <p>4 Q. And you're --</p> <p>5 A. I don't know whether the toxicity of</p> <p>6 NDMA is necessarily related to the methylating</p> <p>7 species as opposed to formaldehyde. I don't think</p> <p>8 that's known.</p> <p>9 Q. Doctor, what percentage of the NDMA</p> <p>10 metabolizes to formaldehyde as opposed to the</p> <p>11 methylating species?</p> <p>12 A. One hundred percent.</p> <p>13 Q. So 100% is formaldehyde and 100% is</p> <p>14 this methylating species?</p> <p>15 A. Yes.</p> <p>16 Q. Two halves equal three? Doctor, how</p> <p>17 can two things both be 100%?</p> <p>18 A. For each? Okay. Maybe I wasn't too</p> <p>19 clear, but for each molecule -- let's put it this</p> <p>20 way: The first thing that happens is that the</p> <p>21 methyl -- hold on a second, please.</p> <p>22 MR. FOWLER: Yes, sir.</p> <p>23 (Discussion off the stenographic</p> <p>24 record)</p> <p>25 THE WITNESS: I'm back.</p>

<p style="text-align: right;">Page 337</p> <p>1 A. So the first thing that happens is 2 that the P450 catalyzes the hydroxylation of the 3 methyl group to give it alpha hydroxymethyl 4 dimethylnitrosamine. That intermediate has a 5 lifetime of a few seconds and it decomposes 6 spontaneously to formaldehyde and methane 7 diazohydroxide. Methane diazohydroxide is the 8 methylating agent in its DNA and the formaldehyde 9 is formaldehyde. 10 So for every molecule of NDMA that is 11 metabolized, you get one molecule of formaldehyde 12 and one molecule of methane diazohydroxide, 13 methylating agent. 14 THE WITNESS: Hold on a second. 15 MR. FOWLER: Yes, sir. 16 THE WITNESS: Okay. 17 Q. Does the formaldehyde form the 18 O6-methylguanine mutation, sir? 19 A. No. That comes from the methylating 20 agent. 21 Q. Yes, sir. 22 In any of the literature that you've 23 relied upon in your report or that you've reviewed 24 and is not part of your report, has any literature 25 about NDMA -- let's talk about the dietary</p>	<p style="text-align: right;">Page 339</p> <p>1 Any dispute there, sir? 2 A. No. 3 Q. And Doctor, you see if it's assumed 4 that NDMA is cleared solely by hepatic metabolism, 5 the bioavailability will depend upon the clearance 6 and the hepatic blood flow. 7 You agree with that as well, right? 8 A. Sure. 9 Q. And is the blood flow in primates -- 10 in particular, the hepatic blood flow in 11 primates -- the same, greater, lesser than humans, 12 sir? 13 A. I don't know. 14 Q. Wouldn't it be important to 15 understanding anything you want to extrapolate 16 from these pharmacokinetic studies to understand 17 what the hepatic blood flow is in -- 18 A. Probably. Probably would be. 19 So what's your point? 20 Q. That you didn't -- while you're 21 relying on these for the statement that in humans 22 there's high systemic clearance and high oral 23 bioavailability, you didn't make any effort to 24 determine whether that data can be fairly 25 extrapolated from the Gombar studies, did you?</p>
<p style="text-align: right;">Page 338</p> <p>1 studies. 2 Has any literature ever blamed the 3 formaldehyde as being a carcinogenic factor to -- 4 let me leave it at that -- as being a carcinogenic 5 factor in those studies? 6 A. No. In general it's not, no. That's 7 true. 8 Q. Okay. 9 A. No literature. It doesn't mean that 10 it doesn't play a role. Nobody has thought of it. 11 Q. Okay. 12 A. Maybe they thought about it, but if 13 they thought about it, they didn't do anything 14 about it. 15 Q. Fair enough, sir. 16 Let's scroll down that page just a 17 little bit further. Right above the formula, the 18 paragraph starts "In spite of ..." 19 Doctor, you see this statement, "In 20 general, the smaller species" -- and we're talking 21 about the Dr. Gombar's pharmacokinetic studies on 22 things like beagles, hamsters and monkeys even -- 23 it states "In general, the smaller species tended 24 to show lower bioavailability than larger 25 species."</p>	<p style="text-align: right;">Page 340</p> <p>1 A. No, I didn't. 2 Q. If you look -- the last paragraph on 3 this page -- I'm sorry. In that column, sir -- 4 you see wide interspecies -- there you go, that 5 last one in the first column. Perfect. 6 It states "The wide interspecies 7 difference in bioavailability in NDMA is difficult 8 to explain." 9 Do you see that, Doctor? 10 A. Yes. 11 Q. You would agree that there's 12 interspecies differences with humans compared to 13 any of the animals Dr. Gombar studied with his PK 14 analysis. 15 Correct, sir? 16 A. Sure. 17 Q. Doctor, do you believe that the lung 18 plays any role in the clearance of NDMA? 19 A. Administered orally? 20 Q. Yes, sir. 21 A. It seems unlikely, but it could. 22 Q. If we could look to the last 23 paragraph in the second column, do you agree with 24 the statement, Doctor, that it is an 25 oversimplification to focus solely on</p>

<p style="text-align: right;">Page 341</p> <p>1 pharmacokinetics when you're trying to do a risk 2 assessment, if you will, of NDMA's 3 bioavailability? 4 A. Sure. It's complicated. 5 Q. But it says to base risk on dose 6 alone is also an oversimplification. 7 Do you agree with that, sir? 8 A. Well, sure, but I mean, you know, 9 dose response is very important in carcinogenesis. 10 You know, this Gombar study was published before 11 the Peto study, if I'm not mistaken. 12 So, I mean, we do know a lot about 13 the dose response characteristics of NDMA in 14 laboratory animals, particularly rats. Also mice 15 and hamsters. So we know a lot about that, so I 16 mean, you know, this very general statement here 17 was probably made in response to a reviewer, so, 18 you know, just because something is written like 19 in the discussion session of a paper doesn't mean 20 that it's necessarily engraved in stone. So sure, 21 it's an oversimplification to focus solely on 22 pharmacokinetics. 23 MR. FOWLER: We can take that exhibit 24 down. 25 Q. Doctor, returning to your statement</p>	<p style="text-align: right;">Page 343</p> <p>1 Fair statement? 2 MR. SLATER: Objection. 3 You can answer. 4 A. No, that's wrong. You're just 5 talking about all kinds of low-dose studies. 6 Q. Do those studies speak to 7 bioavailability, sir? 8 A. Sure they did, yeah. 9 Q. Bioavailability is -- 10 A. When, you know, you have a low dose 11 given to a rat and it's orally and it's 12 metabolized significantly in the liver, then the 13 bioavailability of the test compound to other 14 tissues is very low. 15 Q. Any such data would have to be 16 extrapolated to humans based upon the hepatic 17 blood flow, correct, sir? 18 A. Well, sure. 19 Q. Any dose given to a mouse or any 20 rodent or other species would have to be adjusted 21 to evaluate a low dose in humans, correct? 22 MR. SLATER: Objection. 23 Lack of foundation. 24 You can answer. 25 MR. FOWLER: Let me withdraw the</p>
<p style="text-align: right;">Page 342</p> <p>1 on page eight of your report where you were 2 attempting to opine that NDMA has a high systemic 3 clearance and high oral bioavailability in humans, 4 the only studies that you're pointing to, if we 5 look at sites 21, 22, 23, 24, 25, it's Gombar, 6 Gombar, Gombar, then a Dr. Anderson article. 7 Is that the -- is there anything 8 else, sir, to support an opinion that there's high 9 systemic clearance and high oral bioavailability 10 of NDMA? 11 A. There are other articles, yeah. I 12 don't think I got them all here. There's quite a 13 bit of literature on pharmacokinetics and NDMA. 14 You know, I was a little selective here. This is 15 not a comprehensive review. But, you know, 16 systemic clearance by the liver is kind of a 17 common observation. 18 Q. You would agree, Doctor, that the 19 systemic clearance in oral bioavailability depends 20 on the dose, correct? 21 A. Yes. 22 Q. And you can point to no study that 23 evaluates a low dose of NDMA and NDEA and arrives 24 at any conclusion about its bioavailability or 25 systemic clearance.</p>	<p style="text-align: right;">Page 344</p> <p>1 question, sir. I think you've answered -- 2 MR. SLATER: Counsel, I'm not looking 3 to argue with you or anything. I just want 4 to establish something so I understand. 5 I asked the videographer how long 6 we're at at this point and how long 7 Mr. Fowler has been going. I think it's 8 probably 45 minutes approximately. 9 MR. FOWLER: We don't have to guess. 10 What's the number? How long have we been on 11 the record? 12 THE VIDEOGRAPHER: If you guys 13 wouldn't mind, I could go off the record so I 14 could give you an exact number. 15 MR. FOWLER: Apparently, that's 16 important right now, so let's do that. 17 THE VIDEOGRAPHER: The time is 6:27. 18 We're going off the video record. 19 (Recess taken) 20 THE VIDEOGRAPHER: The time is 6:33. 21 This begins media seven. 22 You may proceed. 23 Q. Doctor, switching gears again, sir, 24 with regard to the FDA workshop that you 25 participated in, did FDA provide you with any</p>

<p style="text-align: right;">Page 345</p> <p>1 written materials in advance or even the questions</p> <p>2 in advance, sir?</p> <p>3 A. Yes, the questions.</p> <p>4 Q. Did you share those questions with</p> <p>5 anyone?</p> <p>6 A. No.</p> <p>7 Q. What has been marked as Exhibit 12,</p> <p>8 the FDA's summary on that workshop, sir, did you</p> <p>9 get -- did you get an advance copy to review and</p> <p>10 comment upon?</p> <p>11 MR. SLATER: Wasn't he questioned on</p> <p>12 this document already, sir? So now you're</p> <p>13 going back into the FDA document? Okay.</p> <p>14 You can answer the question.</p> <p>15 I'm writing to the court.</p> <p>16 A. Yes. I'm not sure what you mean by</p> <p>17 advance copy.</p> <p>18 Q. Did you get a draft to review and</p> <p>19 comment before FDA published it to the --</p> <p>20 A. Yes. Yes.</p> <p>21 Q. And did you take the opportunity to</p> <p>22 review it?</p> <p>23 A. Yes.</p> <p>24 Q. Did you have any comments or changes?</p> <p>25 A. Nothing -- nothing substantial. I</p>	<p style="text-align: right;">Page 347</p> <p>1 we'd like a copy of the email with your edits to</p> <p>2 the draft summary statement.</p> <p>3 A. I don't think they were specific, but</p> <p>4 anyhow, I'd have to go back and look.</p> <p>5 Q. Fair enough --</p> <p>6 A. It wasn't, like, line 35, change this</p> <p>7 to that. In general --</p> <p>8 Q. Okay. That's helpful. Yes, sir.</p> <p>9 A. -- I agreed with her summary. Very</p> <p>10 comprehensive.</p> <p>11 Q. Right, but you indicated you did have</p> <p>12 changes and you did communicate back to FDA with</p> <p>13 regard to your response to the draft, correct?</p> <p>14 A. I believe so.</p> <p>15 Q. I'll make that request offline, sir.</p> <p>16 At the time that you reviewed the FDA</p> <p>17 summary, did you have the transcripts available to</p> <p>18 you?</p> <p>19 A. I didn't review the transcripts.</p> <p>20 MR. FOWLER: Now, let's put up</p> <p>21 Exhibit 12, the FDA summary. Just a couple</p> <p>22 things I wanted to clarify from your prior</p> <p>23 testimony.</p> <p>24 THE VIDEOGRAPHER: Counsel, I have as</p> <p>25 Exhibit 12 the "Critical Review of Major</p>
<p style="text-align: right;">Page 346</p> <p>1 may have had some minor changes, but in general,</p> <p>2 it was a good summary.</p> <p>3 Q. How did you communicate those changes</p> <p>4 to FDA?</p> <p>5 A. Email with the -- I forgot her name</p> <p>6 right now.</p> <p>7 Q. That's fine, sir.</p> <p>8 Did you send a red line document or</p> <p>9 did you type some summary in an email?</p> <p>10 A. Summary in an email.</p> <p>11 MR. SLATER: Just for the record, I</p> <p>12 object to this entire line of questioning.</p> <p>13 This document was thoroughly addressed by</p> <p>14 Mr. Trischler, so this is clearly</p> <p>15 duplicative.</p> <p>16 The fact that you may be finding a</p> <p>17 different question that's not identical to</p> <p>18 Mr. Trischler's doesn't mean that this</p> <p>19 shouldn't be left alone, as Mr. Trischler</p> <p>20 covered this subject.</p> <p>21 You could continue.</p> <p>22 Q. Do you still have that email, Doctor?</p> <p>23 A. I don't know.</p> <p>24 Q. I will just make a request on the</p> <p>25 record -- and I'll follow up with counsel -- that</p>	<p style="text-align: right;">Page 348</p> <p>1 Sources of Human Exposure." I believe it may</p> <p>2 be 13. Do you mind if I put 13 up to</p> <p>3 confirm?</p> <p>4 MR. FOWLER: Yes, please.</p> <p>5 THEVIDEOGRAPHER: This is Exhibit</p> <p>6 13.</p> <p>7 MR. FOWLER: Okay. Thank you.</p> <p>8 Q. I'll direct your attention to page</p> <p>9 four, last paragraph.</p> <p>10 Doctor, you recall the discussion</p> <p>11 about endogenous and exogenous sources of NDMA?</p> <p>12 Do you recall that, sir?</p> <p>13 A. Yes.</p> <p>14 Q. Do you recall the FDA's statement "To</p> <p>15 calculate the risk, it's imperative to determine</p> <p>16 endogenous formation and understand the</p> <p>17 pharmacokinetics of nitrosamine formation and</p> <p>18 distribution"?</p> <p>19 A. Yes.</p> <p>20 Q. We were just speaking to the</p> <p>21 pharmacokinetic --</p> <p>22 MR. SLATER: Counsel, why are you</p> <p>23 rehashing? This document and this subject</p> <p>24 was already addressed by Mr. Trischler.</p> <p>25 Again, this is duplicative.</p>

<p style="text-align: right;">Page 349</p> <p>1 Q. Do you agree that it's important to 2 understand the endogenous formation and the level 3 of endogenous formation? Correct? 4 A. Yes. 5 Q. And you -- during the panel, when the 6 question is presented to the group, each of you 7 has an opportunity to respond to the question at 8 hand, correct? 9 MR. SLATER: Objection. 10 A. Actually, it was very directed, so I 11 mean certain people -- it was all outlined 12 beforehand who was supposed to respond to which 13 questions and when. It was very scripted. Not 14 scripted, but -- I don't know. I can't think of 15 the word. But basically, you were told when to 16 speak. 17 Q. Doctor, you would agree that the body 18 sees an NDMA molecule as is and doesn't 19 distinguish its origin, whether it be from food, 20 endogenous or from pharmaceuticals, correct? 21 MR. SLATER: Objection. 22 You can answer. 23 A. Yes. 24 Q. And the cumulative exposure that 25 contributes to the response is the essential part</p>	<p style="text-align: right;">Page 351</p> <p>1 considerable endogenous formation of nitrosamines 2 that are not metabolized. So my -- excuse me. 3 Q. Yes, sir. 4 A. My thinking was that we should really 5 learn more about the endogenous formation of 6 nitrosamines such as NDMA that are metabolized and 7 that was the point I was trying to make at the FDA 8 meeting. 9 MR. FOWLER: Thank you. Let's take 10 down this exhibit. Please put up the day one 11 transcript. 12 Q. Doctor, when you were testifying at 13 the FDA panel, you understood that your words were 14 being transcribed just as they are today, correct, 15 sir? 16 A. Yes. 17 Q. And while you weren't under oath, it 18 was your -- you were certainly doing your best to 19 speak the scientific truth, correct? 20 A. Yes. 21 Q. And you said earlier -- several 22 times, I think -- that you had no bias coming into 23 that panel, notwithstanding your retention by 24 Mr. Slater. 25 Do you recall that?</p>
<p style="text-align: right;">Page 350</p> <p>1 of the valuation. 2 Would you agree with that? 3 MR. SLATER: Objection. 4 A. Yes. 5 MR. SLATER: Cumulative exposure was 6 discussed earlier as well, counsel. 7 Q. Doctor, you believe that the -- 8 strike that. 9 During the testimony, you were given 10 an opportunity to respond on the question of 11 endogenous formation. 12 Do you recall what you testified you 13 believe the level was? 14 MR. SLATER: Again, objection. 15 This has been covered. Mr. Trischler 16 went through that presentation. 17 You can answer. 18 I'm continuing to type my email to 19 the court. I regret it that this is 20 necessary. 21 Q. Doctor, do you recall what you 22 testified to the levels of endogenous formation 23 being? 24 A. I don't recall the exact thing, but, 25 you know, the literature indicates that there is</p>	<p style="text-align: right;">Page 352</p> <p>1 A. Correct. 2 Q. So you answered your questions -- 3 MR. SLATER: Counsel, can we stop for 4 a second? I apologize -- 5 MR. FOWLER: No, we can't stop today. 6 We can't stop right now. I'm in the middle 7 of a question. 8 MR. SLATER: I object, Counsel. 9 You're not -- this isn't -- I'm really just 10 telling you -- I need to tell you you have on 11 the transcript -- or on the screen the same 12 transcript and you're asking about bias, 13 which he was questioned about already. 14 So that's the third area where you're 15 now in the same question. Therefore, we're 16 going to stop the deposition. This email is 17 going to go to Judge Vanaskie and I'm asking 18 to terminate the deposition because of this 19 conduct -- 20 MR. FOWLER: I'm reclaiming my time. 21 Q. Directing your attention to page -- 22 MR. SLATER: We're done. 23 MR. FOWLER: No, we're not. 24 MR. SLATER: Go off the record. 25 I'm stopping the deposition and we're</p>

Page 353	Page 355
<p>1 going to wait for Judge Vanaskie -- 2 MR. FOWLER: I'm in the middle of a 3 question with this witness. 4 Q. Page 159, please -- 5 MR. SLATER: No, you're not. You're 6 done. 7 Dr. Hecht, don't answer the question. 8 This is harassing and in violation of 9 Judge Vanaskie's order. 10 I'm going to email him. Hopefully 11 he'll be available and then we'll go from 12 there. 13 MR. FOWLER: I'm going to make a 14 proffer on the record that I'm attempting to 15 show that the doctor's testimony at this FDA 16 hearing is completely inconsistent with his 17 testimony today. 18 I'm entitled to show him this 19 transcript and ask him why he testified 20 differently at the FDA. 21 MR. SLATER: I'm directing him not to 22 answer. 23 MR. FOWLER: If you want to call the 24 Judge on that, we can. 25 MR. SLATER: Please stop the record.</p>	<p>1 to a stop time -- 2 MR. SLATER: Sorry. You're so angry. 3 Don't be so angry. I'm just trying to -- 4 MR. FOWLER: You've been screaming 5 since I started questioning this witness. 6 MR. SLATER: You know, I feel bad for 7 the court reporter. 8 I don't know what to tell you. If 9 you want me to talk, I will. If you want to 10 talk, you can. But I'm trying to type and 11 email on my iPhone. 12 I think that the ruling has been 13 violated. I think I have good grounds for a 14 protective order. I'm asking for one. 15 THE VIDEOGRAPHER: Would both sides 16 like me to go off the video record? 17 MR. SLATER: Do you have my proffer, 18 Madam Court Reporter? 19 THE COURT REPORTER: I have what you 20 guys have been saying. 21 MR. FOWLER: Fair enough. Thank you. 22 MS. KAPKE: This is Kara Kapke. I 23 also have a few follow-up questions, but they 24 should not last more than ten to 15 minutes. 25 MR. SLATER: Ten to fifteen minutes?</p>
Page 354	Page 356
<p>1 I'm writing to Judge Vanaskie. 2 MR. FOWLER: I would further proffer 3 I have additional questions based on the 4 doctor's testimony at the FDA hearing, I have 5 questions based upon the doctor's testimony 6 with regard to the Peto study, among others, 7 and moreover, I have questions about 8 Dr. Hecht's testimony with regard to 9 Dr. Johnson's PDE and the threshold. 10 I have areas to cover that have not 11 been fully explored. 12 I'm asking you to reconsider letting 13 us finish this deposition -- 14 MR. SLATER: I'm writing to the 15 judge. 16 MR. FOWLER: I don't -- you can keep 17 telling me that, Adam. I'm asking you to 18 reconsider and let us finish this deposition. 19 I don't think we're wasting anyone's time 20 other than right now. 21 MR. SLATER: You can't commit to a 22 stop time. You want to be able to go on 23 forever -- 24 MR. FOWLER: How can I commit to a 25 stop time, Adam? I've never heard you commit</p>	<p>1 Okay. 2 MS. KAPKE: Five to ten probably. 3 Maybe not even that long. 4 MR. SLATER: I'm just changing my 5 email. Thank you. 6 THE VIDEOGRAPHER: Counsel, would 7 everyone like me to go off the video? 8 MS. LOCKARD: Yes. Off the record. 9 And can you give us a count of how long we've 10 been going? 11 This is Victoria Lockard speaking. 12 THE VIDEOGRAPHER: The time is 6:45. 13 We're going off the video record. 14 (Recess taken) 15 THE VIDEOGRAPHER: The time is now 16 657. 17 This begins media eight. 18 You may proceed. 19 MR. FOWLER: Can I please get that 20 exhibit back? Day one transcript, FDA panel. 21 Please turn to page 159. 22 Q. When we stopped, Doctor, I was asking 23 you if you recalled what you said at the time of 24 the panel about the endogenous production. 25 Let me direct you to lines 16 to 20.</p>

<p style="text-align: right;">Page 357</p> <p>1 You state "So I think with regard to 2 the question of endogenous formation, which is 3 critical here because there are really high levels 4 in endogenous formation, maybe we do not have to 5 be that concerned about the low levels present in 6 drugs." 7 Have I read your testimony correctly, 8 Dr. Hecht? 9 A. Yes. 10 MR. SLATER: Before you answer, 11 Doctor, objection. 12 I'm asking you to put the full page 13 up there so Dr. Hecht can see the full 14 context, not just this little snippet. Let's 15 give him the whole page, let's let him see 16 the context and -- 17 MR. FOWLER: Absolutely. 18 Q. So Doctor, the lead-up question for, 19 as you recall, had to do with the endogenous 20 formation of NDMA [sic] and speaking about the 21 biomarkers and the adducts. 22 The question before you responded was 23 "Can we have more discussion of what you think of 24 all the biomarkers that you have discussed today 25 that could be more appropriate for nitrosamines?"</p>	<p style="text-align: right;">Page 359</p> <p>1 A. Not NDMA in particular. So what I 2 was referring to in that panel discussion was that 3 there's significant of data for the endogenous 4 formation of nitrosoproline and other nitrosamines 5 that are not metabolized. We could determine this 6 by simply measuring other levels in urine after 7 giving people the precursors and sodium nitrite, 8 as an example. 9 For dimethylnitrosamine and other 10 dialkyl nitrosamines, which are extensively 11 metabolized, we don't know how much endogenous 12 formation there is and what I was trying to say in 13 the FDA meeting was that what a real need that we 14 have is to develop the technology by which we 15 would be able to accurately determine how much 16 endogenous formation there was of compounds like 17 dimethylnitrosamine. 18 So, you know, I was speculating. I 19 speculated that the amount that's formed 20 endogenously might be greater than the exogenous 21 amounts, but we don't know and that was my point. 22 We need research. That was my point. Nothing 23 else. 24 Q. Have you completed -- 25 A. I didn't say that there was -- I</p>
<p style="text-align: right;">Page 358</p> <p>1 As your counsel said, you start your 2 answer "I think DNA adducts would be good to look 3 at. You think we have the technology to reliably 4 quantify DNA adducts with high-res mass 5 spectrometry and we also have the knowledge based 6 on years of study about artifact formation." 7 Then you state what you said about 8 the endogenous formation. 9 Does this refresh your recollection 10 of how you characterized the endogenous formation 11 of NDMA at the FDA panel, sir? 12 A. Yes. 13 MR. SLATER: Objection. 14 Before you answer, Doctor, please let 15 me object. 16 Objection. Okay? Objection. Lack 17 of foundation. It's a very misleading 18 question, but we'll come back to it, 19 Mr. Fowler. You and I both know that. 20 You can answer, Dr. Hecht. 21 Q. Doctor, do you recall this discussion 22 at the FDA panel? 23 A. Yes. 24 Q. And do you recall the issue of what 25 levels of endogenous formation NDMA there is?</p>	<p style="text-align: right;">Page 360</p> <p>1 didn't say that there was higher endogenous 2 formation or that there was lower endogenous 3 formation. I didn't say any of these things. 4 What I said was that we need to 5 develop the technology, the research to assess 6 endogenous formation. That way, we would be able 7 to know whether the endogenous formation of 8 compounds like dimethylnitrosamine really was. 9 Right now, we don't know what it is. 10 So that was my -- that was a message I was trying 11 to deliver. 12 Q. Have you completed your response, 13 Doctor? 14 A. Yes. 15 MR. FOWLER: Can I have that sentence 16 that begins with "So ..." blown up, now that 17 we've seen the whole page? 18 MR. SLATER: I'd like to keep the 19 whole page on the screen, frankly, because 20 now we can't see the full context. 21 Q. Doctor, can you read if we don't blow 22 that up okay? 23 A. Yes. 24 Q. Okay. 25 You see the sentence "So I think with</p>

<p style="text-align: right;">Page 361</p> <p>1 regard to the question of endogenous formation</p> <p>2 ..." that we were looking at?</p> <p>3 A. Yes.</p> <p>4 Q. Okay.</p> <p>5 You state "which is critical here."</p> <p>6 Are you talking about here being the</p> <p>7 issue with NDMA and valsartan?</p> <p>8 MR. SLATER: Objection.</p> <p>9 Lack of foundation.</p> <p>10 A. No. I was talking about generally.</p> <p>11 Okay? Not necessarily about valsartan. I was</p> <p>12 talking about generally for nitrosamines.</p> <p>13 Okay?</p> <p>14 Q. Okay, sir.</p> <p>15 A. We know --</p> <p>16 Q. You've answered the question --</p> <p>17 MR. SLATER: Stop.</p> <p>18 Please continue to answer, Doctor.</p> <p>19 A. Let me finish?</p> <p>20 Q. Certainly, Doctor.</p> <p>21 A. We know from a significant amount of</p> <p>22 data that there is endogenous formation,</p> <p>23 nitrosoproline and other nitrosamines that are not</p> <p>24 metabolized. We can determine this readily. It</p> <p>25 has been done. There's a lot of solid data out</p>	<p style="text-align: right;">Page 363</p> <p>1 panel discussion was that we need to develop the</p> <p>2 technology and do the experiments so we can find</p> <p>3 out the extent of formation of -- of endogenous</p> <p>4 formation -- of dimethylnitrosamine and other</p> <p>5 dialkyl nitrosamines that are rapidly metabolized.</p> <p>6 That's what I was trying to say.</p> <p>7 Q. Yes, I've gotten that, Doctor. I'm</p> <p>8 focused now on how you concluded the sentence,</p> <p>9 that "Maybe we don't have to be concerned about</p> <p>10 the low levels present in the drugs."</p> <p>11 Can you explain that, please?</p> <p>12 A. You're not listening because I have</p> <p>13 explained it. Okay? Listen to what I'm saying.</p> <p>14 Okay?</p> <p>15 If the amount of endogenous formation</p> <p>16 of dimethylnitrosamine turn out to be very high,</p> <p>17 then we wouldn't have to be concerned. But we</p> <p>18 don't know.</p> <p>19 Q. Thank you, Doctor.</p> <p>20 A. We don't know. We have zero data.</p> <p>21 Q. Well, respectfully, you disagree with</p> <p>22 the data that your colleague presented at the FDA</p> <p>23 panel as to the level of 400 micrograms in the --</p> <p>24 produced endogenously.</p> <p>25 You just disagreed with that.</p>
<p style="text-align: right;">Page 362</p> <p>1 there. We don't have this data for the dialkyl</p> <p>2 nitrosamines that are sensibly metabolized such as</p> <p>3 dimethylnitrosamine. We don't have the data.</p> <p>4 So we don't know whether endogenous</p> <p>5 formation of dimethylnitrosamine is zero or</p> <p>6 whether it's the same as the exogenous exposure or</p> <p>7 more. We don't know.</p> <p>8 That was my point. So how it's</p> <p>9 written, how you interpret what's written, I don't</p> <p>10 know. But that was my point.</p> <p>11 Q. Thank you, Doctor.</p> <p>12 Help me understand the last part of</p> <p>13 that sentence, please. "Maybe we do not have to</p> <p>14 be that concerned about the low levels that are</p> <p>15 present in drugs."</p> <p>16 Did I read that correctly?</p> <p>17 A. Yes.</p> <p>18 Q. And we're talking about the NDMA</p> <p>19 levels in the valsartan that you're there at the</p> <p>20 panel for, correct?</p> <p>21 A. That's right.</p> <p>22 MR. SLATER: Lack of foundation.</p> <p>23 Q. Thank you. Did we get that answer --</p> <p>24 A. As I tried to explain, sir, we don't</p> <p>25 know. Okay? What I was trying to say in that</p>	<p style="text-align: right;">Page 364</p> <p>1 A. Four hundred micrograms of what and</p> <p>2 which colleague?</p> <p>3 Q. Doctor -- well, I'll not pronounce</p> <p>4 his name right. It starts with a K. Doctor --</p> <p>5 can you help me, sir?</p> <p>6 A. Kokkinakis.</p> <p>7 Q. Yes, sir.</p> <p>8 Do you recall the slides that he put</p> <p>9 up at the FDA panel on endogenous formation?</p> <p>10 A. Yes, I don't agree with those at all.</p> <p>11 I think they're flawed.</p> <p>12 Q. Right.</p> <p>13 To your point, Doctor, if the level</p> <p>14 is high -- and would you agree a level greater</p> <p>15 than 100 micrograms a day would be considered high</p> <p>16 in the context that you and I are speaking of now?</p> <p>17 A. Yes.</p> <p>18 Q. The point is if it's that high and we</p> <p>19 add 10, 15, 20 micrograms to that endogenous</p> <p>20 supply of NDMA, you would not consider that to be</p> <p>21 an increased risk of cancer compared to the</p> <p>22 endogenous source, correct?</p> <p>23 MR. SLATER: Objection.</p> <p>24 A. I don't know what you're talking</p> <p>25 about, risk of cancer. I don't know. I mean, the</p>

<p style="text-align: right;">Page 365</p> <p>1 point is -- the point that I'm making -- and this 2 is what I believe. Okay? 3 In this deposition, we don't have 4 reliable data on endogenous formation of 5 dimethylnitrosamine and until we have that data, 6 we cannot say that the exogenous formation such as 7 through valsartan is unimportant. We can't say 8 that because we don't have the data. The data 9 that Kokkinakis quoted, I do not believe it's 10 correct. 11 Q. Doctor, do you agree that the panel 12 and FDA was concerned that it would make no sense 13 to the public, including the scientific informed 14 public like yourself, that if FDA set a limit of 15 NDMA at, like, 96 nanograms and the body is 16 producing 400 micrograms a day, that it could 17 erode the confidence in FDA's risk assessments 18 because that would make no sense to the public? 19 Do you recall that discussion? 20 MR. SLATER: Objection. 21 A. Well, sure it would, but we don't 22 have the data. 23 Q. Right. 24 A. If we had -- if we had reliable 25 accepted data on, you know, that NDMA was formed</p>	<p style="text-align: right;">Page 367</p> <p>1 necessity or food voluntarily. 2 Do you see that, Doctor? 3 A. Yes. 4 MR. SLATER: Objection. 5 Lack of foundation. 6 Inaccurately read. 7 Q. You don't disagree with that, Doctor, 8 right? That's what you and I have been speaking 9 about? 10 MR. SLATER: Objection. 11 A. We need the data. You know, we need 12 the data. Intake from water is very unclear and 13 endogenous formation is very unclear. 14 The only place where we really have 15 reliable data, you know, other than valsartan and 16 the other drugs obviously is food. 17 Q. Yes, sir. 18 But my question was actually do you 19 agree that the issue here was that it could send a 20 confusing message if FDA is setting an acceptable 21 intake limit that is far below what our body 22 creates naturally? 23 That's my question, sir. 24 A. Sure, but we don't have the data and 25 they know that. They know that --</p>
<p style="text-align: right;">Page 366</p> <p>1 to the extent of 400 micrograms per day in humans, 2 then FDA would not have put out the thing about 3 96 nanograms. 4 Q. Did FDA impanel this workshop so that 5 they might understand and get scientific input 6 from leaders in the different areas about what 7 these levels are? Isn't that why it was one of 8 the questions posed? 9 A. Yes. 10 MR. FOWLER: Let me have day two 11 transcript, please. 12 Q. Directing your attention to page 15, 13 we're going to look at line nine through 18. It 14 states here, Doctor -- I hope you can see it 15 because I don't want to blow it up, I want to 16 leave the whole page there. 17 It states that the balance of 18 evidence seems to be that the amount consumed by 19 the drugs -- consumed in drugs is minuscule or at 20 least very much smaller than one expects from 21 intake in water and especially in foods and I 22 think it would send a confusing message to 23 consumers, citizens in general, to tell them that 24 the body somehow knows whether a given molecule, 25 any given nitrosamine comes from a drug taken by</p>	<p style="text-align: right;">Page 368</p> <p>1 MR. SLATER: Counsel, stop. 2 A. That's why they made the 3 96 nanograms. 4 MR. SLATER: Counsel, we're going to 5 stop the deposition. 6 A. I mean, really, honestly, we have 7 been -- we have been through this before. 8 MR. FOWLER: I honestly couldn't hear 9 either one of you. 10 THE WITNESS: I'm starting to agree 11 with Adam. 12 MR. FOWLER: I couldn't hear Adam or 13 you, sir. 14 MR. SLATER: Judge Vanaskie has just 15 asked to call -- Mr. Fowler, we're 16 breaking -- let's go off the record. 17 Judge Vanaskie has asked us to 18 include him in a phone conference and he gave 19 the number. We need to call him. I don't 20 have a call in number that I can give to 21 anyone, so I don't know what to do. We got 22 to get him on the phone. He wants to speak 23 right now. 24 THE VIDEOGRAPHER: Would you like to 25 go off the video first?</p>

<p style="text-align: right;">Page 369</p> <p>1 MR. SLATER: That's fine.</p> <p>2 THE VIDEOGRAPHER: The time is 7:12.</p> <p>3 We're going off the video record.</p> <p>4 (Recess taken)</p> <p>5 THE VIDEOGRAPHER: The time is now</p> <p>6 727.</p> <p>7 This begins media nine.</p> <p>8 You may proceed.</p> <p>9 Q. Dr. Hecht, do you have an opinion</p> <p>10 whether or not NDMA is a threshold compound?</p> <p>11 Do you understand the question?</p> <p>12 A. Threshold compound? You mean whether</p> <p>13 there's a threshold for carcinogenicity?</p> <p>14 Q. Yes, sir.</p> <p>15 MR. SLATER: Objection.</p> <p>16 Asked and answered.</p> <p>17 You can answer.</p> <p>18 A. I don't know of any evidence that</p> <p>19 there is.</p> <p>20 Q. Do you have an opinion one way or the</p> <p>21 other, sir?</p> <p>22 A. I believe there is no threshold based</p> <p>23 on the studies of Peto, Grasso and others.</p> <p>24 MR. FOWLER: Well, let's mark --</p> <p>25 A. The large rat dose response study.</p>	<p style="text-align: right;">Page 371</p> <p>1 you agree that the concept, if you will, of</p> <p>2 permissible daily exposure of PDE, the PDE itself</p> <p>3 is a level below which -- let me start that again.</p> <p>4 The PDE would be considered a</p> <p>5 threshold level in that nomenclature, sir?</p> <p>6 MR. SLATER: Objection.</p> <p>7 This topic was asked and answered and</p> <p>8 covered earlier.</p> <p>9 You can answer.</p> <p>10 A. Repeat the question.</p> <p>11 Q. Is a PDE another term for a threshold</p> <p>12 level?</p> <p>13 A. Essentially, yes.</p> <p>14 Q. I understand you did not read</p> <p>15 Dr. Johnson's article, so is it fair to say that</p> <p>16 you don't know whether that article establishes</p> <p>17 any sort of threshold, sir?</p> <p>18 A. Which article was that?</p> <p>19 Q. Dr. Johnson's 2021 --</p> <p>20 A. I hadn't read that, no.</p> <p>21 Q. Yes, sir.</p> <p>22 So you're not here to say whether or</p> <p>23 not that data demonstrates a threshold at low</p> <p>24 doses?</p> <p>25 A. I'm not, no.</p>
<p style="text-align: right;">Page 370</p> <p>1 They concluded that there was no indication of a</p> <p>2 threshold.</p> <p>3 MR. FOWLER: Let's mark Peto 1991 B.</p> <p>4 Q. Doctor, while that's being called up</p> <p>5 here, I think we're -- as far as our nomenclature</p> <p>6 goes, I think we're in agreement that a threshold</p> <p>7 level is one below which there's no evidence of</p> <p>8 carcinogenicity. Just so we're on the same page,</p> <p>9 sir.</p> <p>10 A. Yes.</p> <p>11 THE VIDEOGRAPHER: Counsel, just</p> <p>12 wanted to check. The document, I just want</p> <p>13 to check.</p> <p>14 The document you're looking for, does</p> <p>15 it have at the top of the page "Cancer</p> <p>16 Research"?</p> <p>17 MR. FOWLER: It does. It's called</p> <p>18 "Dose and Time Relationships for Tumor</p> <p>19 Induction in the Liver and Esophagus," etc.</p> <p>20 THE VIDEOGRAPHER: Let me know if</p> <p>21 this is the right one here.</p> <p>22 MR. FOWLER: No.</p> <p>23 THE VIDEOGRAPHER: Okay.</p> <p>24 MR. FOWLER: It's 1991 A.</p> <p>25 Q. Doctor, while this is coming up, do</p>	<p style="text-align: right;">Page 372</p> <p>1 Q. And would you defer to a genetic</p> <p>2 toxicologist to interpret such data when</p> <p>3 calculating a PDE?</p> <p>4 MR. SLATER: Objection.</p> <p>5 You can answer.</p> <p>6 A. A genetic toxicologist?</p> <p>7 Q. Yes, sir.</p> <p>8 A. Would I defer to a genetic</p> <p>9 toxicologist? I'm not sure.</p> <p>10 Q. You've never done a benchmark dose</p> <p>11 evaluation, have you, sir?</p> <p>12 A. I think I mentioned this repeatedly</p> <p>13 today.</p> <p>14 MR. FOWLER: Just waiting on Peto,</p> <p>15 sir. I'm just trying not to --</p> <p>16 THE VIDEOGRAPHER: Counsel, I only</p> <p>17 have one document, the one that I pulled up,</p> <p>18 that was labeled with P-E-T-O for Peto.</p> <p>19 MR. FOWLER: Okay, sir. I'll forge</p> <p>20 ahead without it.</p> <p>21 Q. Doctor, do you recall that in the</p> <p>22 Peto study, there was a level of -- let me start</p> <p>23 that again.</p> <p>24 The Peto study was a large cancer</p> <p>25 bioassay, correct?</p>

<p style="text-align: right;">Page 373</p> <p>1 A. Yes.</p> <p>2 Q. It administered a variety of doses,</p> <p>3 some of which until that animal died, correct?</p> <p>4 A. Yes.</p> <p>5 Q. And it had a control group, yes?</p> <p>6 A. Yes.</p> <p>7 Q. And at low doses, if the number of</p> <p>8 subject animals produced fewer tumors than the</p> <p>9 background rate of the control group, would you</p> <p>10 say that there's evidence of a -- that that</p> <p>11 supports evidence of a threshold?</p> <p>12 Do you understand my question, sir?</p> <p>13 A. No.</p> <p>14 Q. It was a bad question. I'll try</p> <p>15 again.</p> <p>16 If the dose levels from let's say</p> <p>17 0.001 through 0.087, as reflected in table seven</p> <p>18 of Peto, produced tumors fewer than the control</p> <p>19 group expressed, do you agree that you cannot</p> <p>20 attribute the tumors produced at those low doses</p> <p>21 to anything other than background?</p> <p>22 MR. SLATER: Objection.</p> <p>23 I object for multiple reasons,</p> <p>24 including you're quoting a table that nobody</p> <p>25 can see and I object to the multiple parts of</p>	<p style="text-align: right;">Page 375</p> <p>1 Q. Why are control groups used in animal</p> <p>2 studies, sir?</p> <p>3 A. Because it gives you a reference</p> <p>4 point to compare to your treated group.</p> <p>5 Q. And why is that important?</p> <p>6 A. Because, you know, there might be</p> <p>7 some tumors that form in the untreated animals for</p> <p>8 reasons other than the material that you're</p> <p>9 administering due to other factors, endogenous</p> <p>10 factors and whatever.</p> <p>11 So you have to have a control group</p> <p>12 because, you know, tumors will develop in various</p> <p>13 organs of animals with old age, laboratory animals</p> <p>14 with old age, so you need the control group as a</p> <p>15 comparison.</p> <p>16 Q. Thank you, sir.</p> <p>17 Let me direct your attention --</p> <p>18 shifting gears back to your report, please -- I'm</p> <p>19 going to direct your attention to page 11.</p> <p>20 Let me know when you're there, sir.</p> <p>21 A. I'm there.</p> <p>22 Q. The middle paragraph -- and this is</p> <p>23 Exhibit 1 -- in the middle paragraph, at the</p> <p>24 bottom, you state "Given sufficient exposure to</p> <p>25 NDMA and NDEA, as with the levels found in the</p>
<p style="text-align: right;">Page 374</p> <p>1 the question.</p> <p>2 You can answer if you can.</p> <p>3 A. I really can't answer that without</p> <p>4 looking at the data. But I do recall very</p> <p>5 specifically that Peto said either in the abstract</p> <p>6 or in the discussion that there was no evidence of</p> <p>7 a threshold, quote, unquote.</p> <p>8 Peto is a statistician who was very</p> <p>9 well respected, so I take his word.</p> <p>10 Q. Yes, sir.</p> <p>11 Doctor, if in an animal study the</p> <p>12 doses produce fewer tumors than the control group,</p> <p>13 can you conclude anything about the causation of</p> <p>14 those low doses, sir?</p> <p>15 A. I would have to look at the data. I</p> <p>16 don't know what data you're talking about.</p> <p>17 Q. Is there any conceivable study that</p> <p>18 you can imagine where the dose group revealed</p> <p>19 fewer tumors than the control group and a</p> <p>20 causation determination can be made? Can you</p> <p>21 envision anything like that, sir?</p> <p>22 MR. SLATER: Objection.</p> <p>23 Multiple reasons.</p> <p>24 You can answer.</p> <p>25 A. I don't know.</p>	<p style="text-align: right;">Page 376</p> <p>1 contaminated valsartan (see below) the formation</p> <p>2 of these DNA adducts would be sufficient to cause</p> <p>3 mutations in cancer in exposed humans."</p> <p>4 Have I read that correctly, sir?</p> <p>5 A. Yes.</p> <p>6 Q. You would agree, sir, that the number</p> <p>7 of adducts is dispositive for a cell to undergo a</p> <p>8 malignant transformation; isn't that correct?</p> <p>9 A. Is dispositive? What was your -- I</p> <p>10 didn't hear --</p> <p>11 Q. I'll rephrase, sir.</p> <p>12 A. The number of adducts is what?</p> <p>13 Q. There is a minimum number of adducts</p> <p>14 that must be -- that exist in a cell before it</p> <p>15 undergoes a malignant transformation, correct?</p> <p>16 A. A minimum number? Sure. I mean,</p> <p>17 there is a number. We don't necessarily know what</p> <p>18 it is.</p> <p>19 Q. Yes, sir. And one O6-methylguanine</p> <p>20 mutation can be the result of one metabolized NDMA</p> <p>21 molecule, right?</p> <p>22 A. Correct.</p> <p>23 Q. Do you have any reason to dispute</p> <p>24 that there are roughly 600 adducts of</p> <p>25 O6-methylguanine at any given time in a cell</p>

<p style="text-align: right;">Page 377</p> <p>1 absent exogenous NDMA?</p> <p>2 A. Where did you get that from?</p> <p>3 Q. My question is do you have any reason</p> <p>4 to dispute that, sir?</p> <p>5 A. Yes.</p> <p>6 Q. What is your basis?</p> <p>7 A. I don't know where you got that</p> <p>8 number from. Just made it up or what? Where did</p> <p>9 you get the number 600 from?</p> <p>10 Q. You agree there's a baseline number</p> <p>11 of O6-methylguanine adducts in a cell at any given</p> <p>12 time, sir, right?</p> <p>13 A. Baseline number? What is that?</p> <p>14 THE WITNESS: Hold on, sir.</p> <p>15 (Discussion off the stenographic</p> <p>16 record)</p> <p>17 Q. I'll move on, Doctor.</p> <p>18 A. Sorry.</p> <p>19 Q. Referring to page 11, I'm just</p> <p>20 interested in what the number of DNA adducts you</p> <p>21 are referring to in that sentence.</p> <p>22 You don't give any level, sir, and</p> <p>23 that's what I'm asking --</p> <p>24 A. Which sentence now?</p> <p>25 Q. The one we read in page 11 of your</p>	<p style="text-align: right;">Page 379</p> <p>1 the low doses, you know, what's a low dose, what</p> <p>2 are the conditions. There are many factors, but</p> <p>3 we know that DNA repair is important.</p> <p>4 You know, there's a lot of hand</p> <p>5 waving in your statement.</p> <p>6 Q. Thank you, sir.</p> <p>7 I've now found where the 600 came</p> <p>8 from -- I apologize -- earlier.</p> <p>9 Were you familiar with an article by</p> <p>10 Dr. Krause and McKeene, et al, from 2019 entitled</p> <p>11 "Immunological and Mass Spectrometry Approaches to</p> <p>12 Determine Thresholds of Mutagenic DNA Adduct</p> <p>13 O6-methylguanine and VBo"?</p> <p>14 Are you familiar with that article,</p> <p>15 sir?</p> <p>16 A. Doesn't strike a bell offhand.</p> <p>17 Q. Okay.</p> <p>18 Thank you, sir.</p> <p>19 Doctor, do you agree that potency,</p> <p>20 the existence of a threshold and dose response are</p> <p>21 toxicology issues, sir?</p> <p>22 A. Yes.</p> <p>23 Q. And because you are not a</p> <p>24 toxicologist, you're not qualified to render</p> <p>25 opinions on potency existence of a threshold or</p>
<p style="text-align: right;">Page 378</p> <p>1 report, "Given sufficient exposure to NDMA and</p> <p>2 NDEA, as with the levels found in the valsartan,</p> <p>3 the formation of these DNA adducts would be</p> <p>4 sufficient to cause mutations."</p> <p>5 My question is how many adducts, sir?</p> <p>6 A. I don't know. One. One adduct in</p> <p>7 theory.</p> <p>8 Q. I'm sorry. You broke up.</p> <p>9 One more time?</p> <p>10 A. One adduct in theory is enough.</p> <p>11 Q. You would agree that one adduct is</p> <p>12 subject to DNA repair, correct?</p> <p>13 A. Yes.</p> <p>14 Q. And if repaired, no risk of</p> <p>15 carcinogenicity, correct?</p> <p>16 A. Not from that particular pathway,</p> <p>17 correct.</p> <p>18 Q. Do you disagree that DNA repair can</p> <p>19 and does create a threshold level when exposed to</p> <p>20 low doses of NDMA?</p> <p>21 MR. SLATER: Objection.</p> <p>22 You can answer.</p> <p>23 A. It's a very general question. I</p> <p>24 mean, there's no doubt that DNA repair is</p> <p>25 important. You know, when you say does it affect</p>	<p style="text-align: right;">Page 380</p> <p>1 dose response; isn't that correct, sir?</p> <p>2 MR. SLATER: Objection.</p> <p>3 You can answer.</p> <p>4 A. That depends what you mean by</p> <p>5 qualifications. I'm not a toxicologist. That's</p> <p>6 true. I don't know that that necessarily excludes</p> <p>7 me from having opinions.</p> <p>8 Q. Yes, sir.</p> <p>9 Would you defer to a toxicologist as</p> <p>10 to the existence of a threshold for NDMA and NDEA?</p> <p>11 MR. SLATER: Objection.</p> <p>12 You can answer.</p> <p>13 A. That would depend who the</p> <p>14 toxicologist was.</p> <p>15 Q. Fair point, sir. Thank you.</p> <p>16 Doctor, do you agree that or disagree</p> <p>17 that the DNA adducts that we're speaking about,</p> <p>18 this O6-methylguanine, those adduct measurements</p> <p>19 do not define the location of the adduct in the</p> <p>20 genome.</p> <p>21 Is that a true statement?</p> <p>22 A. Yes.</p> <p>23 Q. Given that cells have evolved</p> <p>24 efficient measures to keep gene coding sequences</p> <p>25 damage free, it's not possible to currently say if</p>

<p style="text-align: right;">Page 381</p> <p>1 DNA adducts accrue in a linear fashion in the 2 coding sequences. 3 Do you agree with that? 4 A. Yeah, yes. 5 Q. And for the jury -- I'm sorry. 6 A. Yeah. 7 Q. For the jury's purpose, by saying it 8 does not accrue in a linear fashion, that means if 9 you're adding two more NDMA molecules that it will 10 not -- let me start that again. 11 If you double the NDMA molecules, it 12 doesn't result in a linear uptick of the 13 mutations, correct, sir? 14 MR. SLATER: Objection. 15 You can answer. 16 A. You know, that's a complicated 17 question because we know that the dose response 18 for NDMA -- and NNK, for that matter -- in mice is 19 a hockey stick -- 20 Q. Yes, sir. 21 A. -- kind of picture because when the 22 O6-methylguanine DNA methyl transfer is 23 succeeded -- in the activity that is succeeded -- 24 then the cancerous mutations will increase more 25 rapidly, so it's not linear. It's more like this.</p>	<p style="text-align: right;">Page 383</p> <p>1 identification.) 2 (Whereupon, Exhibit 26 was marked for 3 identification.) 4 Q. Do you recall this issue coming up in 5 the FDA panel, sir? 6 A. Not right now, I don't, but sure, I 7 probably do. 8 Q. I'll try to refresh your 9 recollection. Look at day one and I'll direct 10 your attention, please, to page 143 and in 11 particular, directing you to line 15 through 19. 12 Do you see your name there? 13 A. Yes. 14 Q. I could have it blown up so you could 15 take your time to look at it. 16 So you say "I agree. Considering the 17 low levels that we are going to be observing, 18 additivity is definitely the default assumption of 19 the molar amounts that are present, so I agree 20 with everything that has been said about 21 additivity." 22 Do you see that, sir? 23 A. Yes. 24 Q. And are you familiar -- I'm sorry? 25 A. That's what I said.</p>
<p style="text-align: right;">Page 382</p> <p>1 Q. And a hockey stick, I've got a couple 2 behind me, they're long and flat and then the 3 blade goes up at the end, correct, sir? It's a 4 line with an uptick at the end where the hockey 5 blade would be? That's how it gets its name? 6 A. Yes. You have a slowly increasing 7 amount which would be similar to the blade and 8 then when you reach a certain point, the increase 9 is greater, so that's where the hockey stick comes 10 from. 11 Q. Yes, sir. Thank you. 12 Shifting gears a little bit, Doctor, 13 just to keep moving, do you agree that if more 14 than one nitrosamine are present -- let's do it 15 this way. 16 If NDEA and NDMA are both present in 17 the body at the same time, do you agree that their 18 actions, if you will, will be additive and not 19 synergistic? 20 Do you understand the question, sir? 21 A. Yes, probably. But to tell the 22 truth, I don't think we have good data on that. 23 MR. FOWLER: Can I have the FDA 24 transcript, day one please? 25 (Whereupon, Exhibit 25 was marked for</p>	<p style="text-align: right;">Page 384</p> <p>1 Q. You're not -- you have no -- you're 2 not disagreeing with yourself here today, are you, 3 sir? 4 A. No. 5 MR. FOWLER: Doctor, let me again 6 switch gears. You could take that down, 7 please. 8 Q. With regard to your research on 9 tobacco and cigarette smoking, the -- you would 10 agree that there are -- there have been identified 11 specific cancers which are attributed to cigarette 12 smoking, correct, sir? 13 A. Yes. 14 Q. And I think you testified earlier 15 there's some 70 carcinogens in tobacco, which 16 include certain nitrosamines, yes? 17 MR. SLATER: Objection. 18 A. In tobacco smoke. 19 MR. SLATER: Objection. 20 We're now duplicating questioning 21 exactly. I don't appreciate it. 22 MR. FOWLER: It's just a foundation, 23 Counsel. Trying to orient the doctor as I 24 jump around here. 25 Q. So Doctor, the carcinogens from</p>

<p style="text-align: right;">Page 385</p> <p>1 cigarette smoke, you would agree, are quickly --</p> <p>2 quickly enter the bloodstream upon exposure.</p> <p>3 Do you agree with that?</p> <p>4 A. Yes.</p> <p>5 Q. And as a result of --</p> <p>6 A. For the most part.</p> <p>7 Q. Fair enough.</p> <p>8 As a result, they travel throughout</p> <p>9 the body's tissues, the arterial system, back,</p> <p>10 venous system.</p> <p>11 It's everywhere, correct, sir?</p> <p>12 A. It's a very general statement. You</p> <p>13 know, each carcinogen behaves differently. For</p> <p>14 example, some may be retained in the lung</p> <p>15 particles. There may be other factors that affect</p> <p>16 the absorption into the bloodstream.</p> <p>17 Q. Based upon your research, Doctor, you</p> <p>18 agree that NDMA, as one of those nitrosamines,</p> <p>19 likewise enters the blood and is transported to</p> <p>20 various tissue systems in the blood, correct?</p> <p>21 A. Yes.</p> <p>22 Q. And throughout your research of</p> <p>23 cigarette smoke and tobacco, none of your studies</p> <p>24 or any studies that you have seen has identified</p> <p>25 cigarette smoke-induced tumors as being caused by</p>	<p style="text-align: right;">Page 387</p> <p>1 You can answer.</p> <p>2 A. We don't know the answer to that.</p> <p>3 Q. You agree that the nitrosamines in</p> <p>4 tobacco smoke or smokeless tobacco have different</p> <p>5 carcinogenic presentations when administered</p> <p>6 differently, correct?</p> <p>7 A. Yes and no. It's not really correct.</p> <p>8 It depends -- you can't generalize. Okay? I know</p> <p>9 too much about this. Some of them -- NNK for</p> <p>10 example, will affect the lung almost independent</p> <p>11 of the root of administration, seemingly given by</p> <p>12 insulation into the bladder and affects mainly the</p> <p>13 lung. NNN, on the other hand, will affect the</p> <p>14 oral cavity and esophagus when given in drinking</p> <p>15 water.</p> <p>16 Q. I'm sorry.</p> <p>17 A. It's hard to generalize.</p> <p>18 Q. For each cancer that you would agree</p> <p>19 is caused by cigarette smoke, do you agree that</p> <p>20 that determination was based upon actual data and</p> <p>21 testing and an evaluation of human tissue and</p> <p>22 tumors to make that causation connection?</p> <p>23 A. Epidemiology, yes.</p> <p>24 Q. Well, I'm speaking of actual lab</p> <p>25 science, Doctor.</p>
<p style="text-align: right;">Page 386</p> <p>1 NDMA.</p> <p>2 Isn't that true?</p> <p>3 A. Correct.</p> <p>4 Q. In fact, it's been your publication</p> <p>5 that the nitrosamines NNN, NNK and there may be a</p> <p>6 couple more, are the responsible nitrosamines for</p> <p>7 the cancers that cigarette smoking causes.</p> <p>8 Is that a fair statement?</p> <p>9 A. No. I've never excluded other</p> <p>10 nitrosamines.</p> <p>11 Q. Okay.</p> <p>12 A. I presented data that supports the</p> <p>13 concept that NNN and NNK cause DNA damage and</p> <p>14 cancer in smokers and also smokeless tobacco</p> <p>15 users, but I've never excluded other nitrosamines</p> <p>16 whatsoever.</p> <p>17 Q. Thank you for that clarification,</p> <p>18 sir.</p> <p>19 Can you explain why it is if NDMA is</p> <p>20 transported through the blood from the cigarette</p> <p>21 smoke why there's not any evidence that NDMA</p> <p>22 causes cancer in these various tissues that it</p> <p>23 reaches through the cigarette smoke as a result of</p> <p>24 the cigarette smoke, sir?</p> <p>25 MR. SLATER: Objection.</p>	<p style="text-align: right;">Page 388</p> <p>1 A. Well, you were talking about</p> <p>2 causation.</p> <p>3 Q. Yes, sir.</p> <p>4 A. So, you know, the first thing in</p> <p>5 causation is usually epidemiology.</p> <p>6 Q. For cancers that are known to be</p> <p>7 caused by cigarette smoke, sir, have the</p> <p>8 determinations as to the specific types of cancer,</p> <p>9 to your knowledge, been evaluated in a -- by</p> <p>10 pathologists in the laboratory to reach any</p> <p>11 conclusions at all, sir?</p> <p>12 A. Repeat your question.</p> <p>13 Q. Well, outside of epidemiology</p> <p>14 evidence, I'm trying to understand whether the</p> <p>15 causal link between cigarette smoke and these</p> <p>16 cancers that you've identified has been identified</p> <p>17 through toxicology studies of human tissue in in</p> <p>18 vivo, in vitro, but using human tissue to make</p> <p>19 that determination?</p> <p>20 A. Yes, absolutely.</p> <p>21 Q. Okay. And -- I'll just leave it at</p> <p>22 that.</p> <p>23 No, I won't.</p> <p>24 There's no such similar study with</p> <p>25 regard to any determination of NDMA and any</p>

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<p>1 cancers that it could allegedly cause in humans, 2 correct? 3 A. Oh, there are multiple studies of 4 NDMA metabolism by human tissues, organ culture 5 studies. Also, sub cellular fractions. Yes, 6 multiple studies published many years ago. 7 Q. Notwithstanding the agreement today, 8 Doctor, you said several times that the level of 9 NDMA in the pharmaceuticals should be zero? 10 A. Yes. 11 Q. Doctor, you don't hold yourself out 12 as any sort of regulatory expert, do you, sir? 13 A. No. 14 Q. Do you know what a drug master file 15 is? 16 A. Not exactly. 17 Q. Do you know what criteria FDA uses 18 whether or not to approve a drug? 19 A. That's not my area. 20 Q. So you have no basis for saying 21 whether or not these drugs have been approved or 22 not or if that number should be zero, do you? 23 MR. SLATER: Objection. 24 A. I have a basis for saying it should 25 be zero. I absolutely have a -- I absolutely have</p>	<p>1 Duplicative. 2 Q. Understanding that valsartan is 3 typically taken chronically, do you have an 4 opinion about whether acute usage of valsartan 5 containing an NDMA or NDEA impurity could cause a 6 person to develop cancer? 7 MR. SLATER: Objection. 8 You can answer. 9 A. Well, it would be more likely from 10 continuous use because, you know, the cumulative 11 dose would be greater. 12 Q. Did you evaluate the animal studies 13 with an eye towards duration of use to make an 14 assessment of how long a person would need to take 15 valsartan containing NDMA or NDEA before that NDMA 16 or NDEA exposure could have caused the person to 17 develop cancer? 18 A. Which animal studies? 19 Q. Any of them. 20 A. No, I didn't attempt to make that 21 evaluation. There are many -- there are many 22 animal studies of NDMA. I guess the one that's 23 most compelling is the Peto study. So we know 24 that very low doses of NDMA given over a long 25 period of time to rats can cause a significant</p>
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<p>1 a basis for saying it should be zero because I've 2 looked at the method of synthesis and I've looked 3 at all the data from CHP and the others and 4 absolutely this never should have happened. We 5 shouldn't be here. It should have been zero. 6 MR. FOWLER: Thank you, Doctor. 7 I don't have further questions. I'll 8 pass the witness to the next questioner. 9 Thank you so much for your time and patience. 10 MR. SLATER: You know, if you told me 11 you had a hockey stick, we would have been 12 more easy going. I don't want to get hit by 13 a hockey stick. 14 MS. KAPKE: Good evening, Dr. Hecht. 15 I'll be very brief. I have a couple of 16 questions. 17 EXAMINATION BY 18 MS. KAPKE: 19 Q. You agreed in response to 20 Mr. Trischler's questions earlier today that 21 valsartan is typically a long-term drug taken 22 chronically. 23 Do you remember that? 24 A. Yes. 25 MR. SLATER: Objection.</p>	<p>1 incidence of tumors. 2 Q. Let's just use that study. I'll just 3 follow up on that. 4 How long of a duration of exposure 5 did the rats have in the Peto study? 6 A. Over two years, I believe it was. 7 Q. Are there any studies that you are 8 relying on that are acute animal studies? 9 A. There are single dose studies of 10 NDMA. Sure. 11 Q. And are -- could you give me -- are 12 they cited in your report? 13 A. No. My report doesn't go into detail 14 and all of the literature on NDMA, which is very 15 extensive, the carcinogenicity literature -- 16 Q. Okay. Let me just back up -- 17 A. -- they're out there. I mean, 18 there's a huge number of studies on NDMA 19 carcinogenicity and laboratory animals. 20 Q. Okay. 21 Let me just back up and ask it this 22 way: You've agreed here multiple times that dose 23 and duration are important. 24 Is there a minimum number of days a 25 person would need to take valsartan that contain</p>

<p style="text-align: right;">Page 393</p> <p>1 NDMA or NDEA in any amount that's relevant to this 2 case before that exposure would cause a person to 3 develop cancer? 4 A. We don't know. In theory, one 5 exposure is sufficient. We don't know a minimum 6 number of days. We don't know that. 7 Q. Are there any studies that you are 8 relying on specifically to allow you to 9 extrapolate to duration of use for only a single 10 day as being appropriate to cause cancer in a 11 human? 12 A. No. I don't believe there is any 13 study like that in a human. 14 Q. Are there any -- 15 A. There are single dose studies in 16 animals -- 17 Q. And -- 18 A. -- of NDMA. 19 Q. Are any of those studies sufficient 20 for you to extrapolate to a person who took one 21 pill of valsartan containing NDMA or NDEA and NDMA 22 or NDEA impurity? Can you cite me any such study 23 that is appropriate to extrapolate? 24 A. No, there's not. 25 Q. What about the same question for a</p>	<p style="text-align: right;">Page 395</p> <p>1 takes one. 2 Q. Well, what I want to get at is what 3 is your opinion to a reasonable degree of medical 4 and scientific certainty as to the duration of 5 exposure that can cause a person to develop cancer 6 following an exposure to valsartan containing an 7 NDMA or NDEA impurity. 8 I'm trying to see if you can put a 9 duration limit on that for me to a reasonable 10 degree of medical and scientific certainty. 11 A. It's very hard to do but, you know, 12 if you force me to give a timeframe, I guess as a 13 minimum I would be, you know, comfortable with one 14 year, but it's very -- very difficult question to 15 answer. 16 MS. KAPKE: Okay. I have no further 17 questions. Thank you. 18 MR. SLATER: Let's go off the record. 19 THE VIDEOGRAPHER: The time is 8:05. 20 We're going off the video record. 21 (Time noted: 8:05 p.m.) 22 (Deposition concluded for the 23 evening.) 24 25</p>
<p style="text-align: right;">Page 394</p> <p>1 single prescription fill for 30 days? 2 A. I don't have that kind of data. That 3 would be -- that would be speculation. 4 Q. And -- 5 A. It's all dose response, so obviously 6 the more frequently the pill contaminated with 7 dimethylnitrosamine was taken, the higher the 8 risk. 9 Q. Would it be fair to say that a person 10 needed to take valsartan containing an NDMA or 11 NDEA impurity for at least a year before that NDMA 12 or NDEA exposure could have caused that person to 13 develop cancer? Would that be a fair statement? 14 A. I don't think we know the timeframe. 15 I mean, the study that we talked about before from 16 Germany covered three years, I believe, and they 17 saw an increased risk of liver cancer, but I don't 18 think we know the timeframe. I mean, in theory, 19 everything lines up wrong. You know, one dose 20 should be enough in theory. 21 Q. Well, in -- 22 A. If everything is wrong, I mean, you 23 know, if your DNA repair is not working right, if 24 you happen to hit the right part of the DNA in the 25 right gene, the right mutation, in theory, it only</p>	<p style="text-align: right;">Page 396</p> <p>1 A C K N O W L E D G M E N T 2 3 I, STEPHEN HECHT, Ph.D., hereby certify that I 4 have read the transcript of my testimony taken under oath 5 in my examination of August 17, 2021; that the transcript 6 is a true, complete and correct record of what was asked, 7 answered and said during this deposition, and that the 8 answers on the record as given by me are true and 9 correct. 10 _____ 11 STEPHEN HECHT, Ph.D. 12 13 Signed and subscribed to 14 before me, this day of 15 2021. 16 _____ 17 Notary Public 18 19 20 21 22 23 24 25</p>

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1 CERTIFICATION

2 I, SARA K. KILLIAN, RPR, CCR, do
3 hereby certify that STEPHEN HECHT, Ph.D.
4 the witness whose examination under oath
5 is hereinbefore set forth, was duly sworn,
6 and that such deposition is a true record
7 of the testimony given by such witness.

8 I FURTHER CERTIFY that I am not
9 related to any of the parties to this
10 action by blood or marriage, and that
11 I am in no way interested in the
12 outcome of this matter.

13 IN WITNESS WHEREOF, I have hereunto
14 set my hand this 23rd day of August, 2021.
15
16
17

<%4268,Signature%>

18 SARA K. KILLIAN, RPR, CCR
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25

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1 ERRATA SHEET

2 VERITEXT NEW JERSEY REPORTING, LLC

3 CASE NAME: In re: valsartan

4 DATE OF DEPOSITION: 8/17/2021

5 WITNESS' NAME: STEPHEN HECHT, Ph.D.

6 PAGE/LINE(S)/ CHANGE REASON

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18 STEPHEN HECHT, Ph.D.

19 SUBSCRIBED AND SWORN TO

20 BEFORE ME THIS _____ DAY

21 OF _____, 2021.

22 _____

23 NOTARY PUBLIC

24 MY COMMISSION EXPIRES _____

25 _____

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[& - 2011]

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